THE FOOD AND DRUGS ACT

JUNE 30, 1906

A STUDY

WITH

TEXT OF THE ACT, ANNOTATED, THE RULES AND REGULATIONS FOR THE ENFORCEMENT OF THE ACT, FOOD INSPECTION DECISIONS AND OFFICIAL FOOD STANDARDS

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PREFACE.

The sentiment back of the Food and Drugs Act is well understood. Every one will agree that, so far as it can be done by legislation, the laws should protect the public from being deceived in the foods which nourish them or in the medicines which are relied on to cure their ills. But to formulate a law which will effectively protect the public without depriving it of freedom to eat what it may choose to eat and to take such remedies as it may wish to take, and without serious disturbance of business conditions, and especially to formulate a Federal law which will do this without transcending the powers conferred on the Congress by the Constitution, is a matter of great difficulty. It is not surprising that the Food and Drugs Act is in some respects difficult to understand. Some of the questions as to its meaning have been answered by expressions of opinion from the Department of Agriculture. Other questions have not been answered and cannot be answered definitely until the meaning of the Act has been determined by the courts. In the matter here contained I have presented such information bearing upon the Act as can be gathered from the decisions given out by the Department of Agriculture, the published expressions of opinion of officials charged with the enforcement of the Act, and the views expressed by those who have studied the Act with especial care in the interest of the manufacturers of and dealers in particular lines of food and drug products.

Whatever sentiments may be entertained as to what ought to be the law and what ought to be done by law with reference to the question of pure foods and pure drugs, the question as to which my clients have wanted information is the

question of what the law is and what it requires of the manufacturer, packer, jobber, and retailer of foods, drugs, medicines or liquors. Information rather than theory is what those who are subject to the requirements of the Act want, and so far as information on the many questions arising under the Act is available, I have collated it and here present it.

ARTHUR P. GREELEY.

WASHINGTON, D. C., *April* 15, 1907.

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The Food and Drugs Act June 30, 1906.

CHAPTER I.

THE GENERAL PURPOSE AND SCOPE OF THE ACT.

1. The Purpose of the Act.

The purpose of the Act is indicated in the title,[1] to prevent so far as within the constitutional power of the Federal Government to do so, the manufacture, sale or transportation of food or drugs which are either so adulterated as to be below the standard of quality expected by the purchaser, or are so poisonous or deleterious in themselves or by reason of the addition to them of poisonous or deleterious coloring or preservatives as to be injurious to health, or which are misbranded or labeled in such a way as to deceive the public as to their character, quality, locality of origin, or manufacture.

The Act has been quite generally regarded as an Act passed in response to the demand of the public for protection from the deception practiced upon consumers by manufacturers of and dealers in foods and drugs. There is some ground for this view; and perhaps it was necessary, in order to secure the passage of the Act, that this idea should have been made more prominent than the facts really warranted and that the comparatively isolated instances of seriously harmful adulteration or misbranding so dwelt upon that

[1] Page 73.

adulteration should be made to appear a general practice. As a matter of fact legislation along the lines of this Act and directed to the same purpose has long been desired by the large majority of manufacturers of and dealers in foods and drugs as a measure of protection against the unfair competition of a small minority who for the sake of temporary gain have been willing to put upon the market foods and drugs which could be sold at a larger profit than the standard goods made and sold by the majority.

Up to the present time no prosecutions have been brought under the Act, but the knowledge that the Act is upon the Statute Books, and that the necessary machinery for its enforcement is already provided for, and that it will be enforced, deliberately perhaps, and with all proper consideration for business interests, but without hesitation or doubt wherever necessary, has already very largely checked the serious adulterations and misbrandings of both foods and drugs.

2. Scope of the Act—Manufacture.

The first section of the Act[2] makes it unlawful to manufacture any article of food or drug which is adulterated or misbranded, within the meaning of the Act, within the District of Columbia or any Territory, the term Territory including, as provided in Section 12[3] the insular possession of the United States, and the Section provides for the punishment of any one violating this provision of the Act.

Being expressly limited to the District of Columbia and the Territories this section of the Act does not apply to the manufacture of any article of food or drug in any State, whether adulterated or misbranded or not. This limitation is in recognition of the fact that Congress is not given by the Constitution the power to regulate manufacturing carried on within a State, and in so far as the manufacture of any article, such for instance as distilled and fermented liquors, oleomargarine, renovated butter and filled cheese,

[2]Page 73. [3]Page 82.

is regulated by Congress, such regulation is incidental to the raising of revenue, or to the exercise of some other power of Congress. But under the Constitution Congress may exercise exclusive legislation in all cases over the District of Columbia, and also has full power as regards the Territories.

This section of the Act became effective January 1, 1907.

3. Scope of the Act—Commerce Within a State.

Section 2[4] is so drawn as to limit the application of the Act, so far as concerns the dealing in adulterated or misbranded foods or drugs within any State, to the strict line of interstate or foreign commerce. It is the *introduction* into any State from any other part of the United States or from any foreign country, of adulterated or misbranded food or drugs, which is prohibited. The offenses punishable under the provisions of this Section are: the *shipment or delivery for shipment* to any point outside the State, either within the United States or in a foreign country, of adulterated or misbranded food or drugs; and the *receiving* from outside the limits of the State and *delivering* to any other person *in original unbroken packages* of any adulterated or misbranded food or drugs so received. It seems clear that the delivery to another person by a dealer in any State of adulterated or misbranded foods or drugs, whether in original unbroken packages or not, which were received by him from a wholesaler or manufacturer's agent in the same State would not render the dealer liable. The wholesaler or manufacturer's agent would be liable in such case for his delivery of the goods to the dealer, provided he received the goods from outside the State. If, however, the dealer receives the goods directly from outside the State and delivers such goods in original unbroken packages to any other person, he would be liable to the penalties provided in this Section.

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4. Scope of the Act—Original Package.

So far as concerns the application of the Act to dealers in any State it is clear that it is essential, in order to constitute an offense under the Act, that the adulterated or misbranded food or drug must have been delivered to another person in the *original unbroken package* in which it was received from outside the limits of the State. The question of what constitutes an *original unbroken package*, is an important one. Under Regulation 2,[5] *original unbroken package* is so defined as to include both the wholesale and the retail package. Apparently this is intended to include, for instance, in canned goods, each individual can as well as also the case or box containing, ordinarily, two dozen cans.

There is no doubt that a single can, bottle or other package shipped separately, whether the package is suitable for the retail trade or not, constitutes an original package.

Schallenberger vs. Pennsylvania, 171 U. S., 1.
In re Beine, 42 Fed. Rep., 545.
In re Harmon, 43 Fed. Rep., 372.
Guckenheimer vs. Sellers, 81 Fed. Rep., 997.

There is no doubt also that an original package within the law of interstate commerce is the package delivered to the carrier at the initial point of shipment, in the exact condition in which it was shipped.

In the case of liquors in bottles, if a number are fastened together, and marked or are packed in a box, barrel, crate or other receptacle, such bundle, box, barrel, crate or receptacle constitutes the original package.

Guckenheimer vs. Sellers, 81 Fed. Rep., 997.

If, as indicated in Regulation 2[5], each unopened can or bottle taken from a case or box introduced into a State as a single package, is to be considered an original package, its sale or delivery to another person must be subject to the

[5] Page 83.

control of Congress to the exclusion of the State in which the sale or delivery takes place and such sale or delivery of unopened cans or bottles so introduced into a State and being adulterated or misbranded, could not be made the basis of prosecution under the food or drug laws of the State. A package cannot be an original package for one purpose and not for another. If a bottle of whiskey introduced into a State as one of a number contained in a case or box, or a package of oleomargarine, renovated butter or filled cheese so introduced into a State, is an original package for the purpose of the Foods and Drugs Act, it is also an original package which as such may be sold within a State without regard to the requirements or prohibition of the laws of the State, except so far as Congress by Act of August 8, 1890, applying to liquor, and by Act of May 9, 1902, applying to oleomargarine, butterine, imitation, process, renovated, or adulterated butter, or imitation cheese, etc., has provided that original packages shall not be exempt from the operation and effect of State laws.

It seems quite impossible to harmonize the evident meaning of Regulation 2 as to what constitutes an original package with the definition of original package as fixed by the decisions of the courts, and it would seem to be a necessary conclusion that the scope of this Act extends only to the sale or delivery within a State of adulterated or misbranded food or drugs in the unbroken original cases or boxes in which they passed from outside the State into it. The provisions of the Act do not apply to foods or drugs whether in original packages or not which are manufactured within a State and sold or delivered to another person within that State.

5. Scope of the Act—Inspection of Materials.

Regulation 16[6], which provides that the Secretary of Agriculture may make inspections, as often as he may deem necessary, to determine whether any filthy, decomposed or

[6]Page 90.

putrid substance is used in the manufacture of food or drug products, and Regulation 8,[7] which requires that the factories in which proprietary foods are make shall be open at all reasonable times to the inspection provided for in Regulation 16,[6] do not seem to have any basis in the Act. The Act does not provide for any such inspection and does not provide any penalty for refusal of permission to inspect. It is doubtful whether a provision contemplating such inspection of any factory located in a State would be constitutional unless expressly limited, as in the Meat Inspection Law of June 30, 1906, to the inspection of materials used in the manufacture of products to be used in interstate or foreign commerce, or as in the Act of May 9, 1902, in reference to renovated butter, where the article manufactured is the subject of a revenue tax. From the fact that inspection is expressly authorized in the Acts referred to, while in the present Act there is no provision for inspection, it would seem clear that no such inspection as provided for in Regulations 16[6] and 8[7] was intended to be authorized.

From the fact, as hereafter pointed out, that there is nothing in the Act which authorizes any proceedings to be brought for any alleged violation of its provisions except upon the result of an analysis or examination of a sample or specimen, it would seem clear that no adulteration which is not disclosed by analysis or examination of the finished food or drug product can be reached or punished under the Act, and that no food or drug product can be deemed to be misbranded if its label correctly states its character or quality as determined by such analysis or examination, whatever means may have been employed to produce the finished product.

6. Scope of the Act—District of Columbia and Territories.

The provisions of the Act undoubtedly extend to adulterated or misbranded foods or drugs sold or offered for

[6]Page 86. [7]Page 90.

sale in the District of Columbia or the Territories and to the exporting or offering for export therefrom of adulterated or misbranded foods or drugs as well as, under Section 1, to the manufacture in the District of Columbia or the Territories, of adulterated or misbranded foods or drugs, irrespective of the question whether or not such adulterated or misbranded foods or drugs are offered for sale or for export in original packages. There is no constitutional limitation upon the control by Congress of commerce in the District of Columbia or the Territories. The retail grocer or other dealer in foods in the District of Columbia, or in any Territory, who sells or offers for sale or for export food products which are adulterated or misbranded, or which are offered for sale under the name of another article, whether actually labeled or not, is liable under the provisions of the Act equally with a wholesale dealer in such adulterated or misbranded foods, whether such foods or drugs are sold in packages or in bulk; and a retail druggist or other dispenser of drugs in the District of Columbia or in any Territory who sells or offers for sale or for export drugs which are adulterated or misbranded is liable under the provisions of the Act, whether he sells them or offers them for sale in original packages or in packages put up by himself, including physicians' prescriptions.

7. Scope of the Act—Inspection of Material in District of Columbia and Territories.

Regulations 16[8] and 8[9] regarding inspection of raw materials and inspection of factories in which proprietary foods are made, are as above pointed out, page 6, without basis in the Act. No doubt such inspection in the District of Columbia and Territories could be provided for by Act of Congress if deemed of sufficient importance, but as the Act now stands no such inspection and no supervision or control of the process or method of manufacture of any article of food or drug is provided for. It is the finished product as

[8]Page 90. [9]Page 86.

put upon the market which, and which alone, is required to be free from adulteration and not to be misbranded.

8. Scope of the Act—Stock on Hand January 1, 1907.

The Act took effect January 1, 1907. So far as it affects dealers in foods or drugs in any State, its provisions apply only to adulterated or misbranded foods or drugs introduced into the State on or after January 1, 1907. To constitute an offense under Section 2 of the Act, the adulterated or misbranded foods or drugs must not only have been delivered to another person in original unbroken packages on or after January 1, 1907, but must have been received by the dealer from another State on or after January 1, 1907.[10]

9. Scope of the Act—Correction of Labels on Hand.

Regulation 17 in paragraph (i) [11] provides for the correction of labels by a supplemental label, stamp, or paster in case of labels printed and on hand which do not comply with the requirements of the Act. The supplemental label, stamp or paster is not necessary on any articles of food or drugs which were within the limits of any State prior to January 1, 1907, and have since that date remained in the State. If sent out of the State, they should be provided with supplemental labels, stamps or pasters if the labels on them need to be corrected. Articles of food or drugs offered for sale in the District of Columbia or the Territories whether received in the District or the Territory after January 1, 1907, or prior to that date, should be provided with such supplemental labels, stamps, or pasters as may be necessary to correct the original label. Articles of foods or drugs received in any State on or after January 1, 1907, and offered for sale in original unbroken packages should be provided with supplemental labels, stamps, or pasters if necessary to correct the original label in any respect.

The correction of original labels by means of supplemental labels, stamps or pasters is permitted until October

[10] F. I. D. 43, Page 107. [11] Page 91.

1, 1907, only. After that date the principal label will be required to be correct.[12]

10. Scope of the Act—Exports.

The Act is intended to apply to adulterated or misbranded foods or drugs exported or offered for export to any foreign country from anywhere within the United States.[13] The Act permits the exporting of foods or drugs which would be held adulterated or misbranded if for domestic use, provided such exported foods or drugs are not in conflict with the laws of the foreign country to which they are intended to be shipped and provided also that the foreign purchaser not only knows what the foods or drugs contain but specifically directs their preparation or packing. The particular purpose of the exception appears to be to permit the use in certain food products for export to foreign countries, of preservatives which are considered deleterious under the strict rulings of the Department of Agriculture.

11. Scope of the Act—Meats and Meat Products.

Regulation 39[14] provides that the regulations shall not apply to domestic meat and meat food products. Meats and meat food products imported from a foreign country, not being provided for under the Meat Inspection Law, are held to be subject to the provisions of this Act.

12. Scope of the Act—Imported Food and Drug Products.

Section 11[15] of the Act provides for the examination of samples of foods and drugs which are being imported into the United States. This Section does not expressly authorize the Secretary of the Treasury to open packages for the purpose of taking samples, but this is authorized in the Act of March 2, 1901, the provisions of which are repeated in subsequent agricultural appropriation Acts, to which the

[12]F. I. D. 43, Page 107. [13]Sec. 2, Page 73. [14]Page 102. [15]Page 81.

present Act is supplemental as regards the matter of imported foods and drugs. Under Section 11[15] of the present Act provision is made for delivery of imported foods and drugs pending examination upon the execution of a penal bond. It should be noted that the Secretary of the Treasury is, under this Section, bound by the result of the examination of the samples delivered to the Secretary of Agriculture and shall refuse delivery if it appears from the samples that the foods or drugs are adulterated or misbranded or are otherwise of a character prohibited by this Section, and no provision is made for any appeal, though no doubt the action of the Secretary of the Treasury refusing delivery would be subject to the supervision of the courts.

This section of the Act applies to imported meats and meat food products as well as to other food products and to drugs.

Under Sections 2933 to 2938, Revised Statutes, relating to imported drugs and medicines provision is made for the forfeiture of all medicinal preparations which do not bear the true name of the manufacturer and the place where they are prepared, and for the refusal of entry to all drugs and medicines which are so far adulterated as to render them inferior in strength and purity to the standard established by the United States and certain foreign pharmacopœias. It is understood that these Sections of the Revised Statutes are considered to be still in force.

13. Scope of the Act—Teas.

Under the Act of March 2, 1897, provision is made for inspection of teas imported into the United States, the Act prohibiting the importation of any merchandise as tea which is inferior in purity, quality and fitness for consumption to standards established by a board appointed by the Secretary of the Treasury. Under the standards so established the coloring of teas is not prohibited and there is no require-

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ment in the Act referred to that color shall be mentioned on the label. It is understood that the present Act will not be construed as preventing the importation or sale in original packages of teas, whether colored or not, which are not inferior to the standards established as provided for in the Act of March 2, 1897. Colored teas, if repacked within the United States and sold in interstate commerce, would seem to be subject to the provisions of the present Act as regards the use of colors, but unless coloring matter is added by the party repacking teas within the United States, the matter is not likely to be made the subject of inquiry by the Department of Agriculture.

14. Scope of the Act—Imported Foods and Drugs—Regulations.

The form of the declaration to be signed by the shipper and attached to the invoice of food or drug products is prescribed by Regulation 33.[16] Information as to other matters affecting importation of foods and drugs is given in Regulations 34 to 38.[17]

15. Scope of the Act—Seizure in Transit.

Section 10[18] of the Act is intended to provide for the seizure of any article of food, drug or liquor which is adulterated or misbranded, while in process of transportation from one State, Territory, District or insular possession to another. The intent of this Section is clear, but it is not clear how or under what circumstances the seizure may be effected. It would seem that the seizure provided for by this Section could be made only after and as a result of an analysis or examination of a sample or specimen by the Bureau of Chemistry of the Department of Agriculture, or under its direction and supervision, on which analysis the article of food, drug or liquor has been held to be adulterated or misbranded. There is nothing in the Act which would warrant the bringing of process of libel for condemnation of

[16]Page 100. [17]Pages 101-102. [18]Page 80.

any article of food, drug or liquor by any district attorney except upon a *prima facie* showing that the provisions of the Act had been violated, and no provision is made for any showing that the provisions of the Act have been violated except the showing provided for in Section 4[19] based upon analysis or examination of a sample or specimen. It is hardly likely that any seizure in transit under Section 10 will be made until further legislation on the matter is had.

16. Effect of the Act.

It is probable that so far as concerns production and consumption within the States, the Act will not be effective to suppress the adulteration or misbranding of food and drug products until supplemented by State legislation. Many of the States have already adopted laws equally as stringent as this Act, some even more stringent, as to what shall be deemed adulteration or misbranding. Nearly all of the States which have not already adopted such laws are likely to do so in the near future. There is a strong movement in favor of the general adoption by the States of uniform food and drug laws on the lines of this Act, and it is probable that this movement will be successful.

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CHAPTER II.

PROCEDURE UNDER THE ACT.

17. Collection of Samples.

The Act does not prescribe in what manner specimens or samples of foods and drugs shall be collected, leaving this to be provided for by the Rules and Regulations made by the Secretary of the Treasury, the Secretary of Agriculture and the Secretary of Commerce and Labor.[20] It should be noticed that the Act does not provide for the opening of packages for the purpose of taking samples, though as above pointed out in respect to imported foods and drugs[21] the Secretary of the Treasury may open packages for this purpose. There seems to be no way under the Act by which specimens or samples may be collected except by purchase and Regulation 3[22] indicates no way except by purchase.

The Act does not contain any provision by which a dealer can be compelled to furnish specimens or samples to an agent of the Department of Agriculture, even upon tender of the price.

As regards the manner of collecting samples, Regulation 3,[22] being made under the authority of the Act, has the force and effect of law and its provisions must be strictly complied with by the collector, if proceedings under the Act are to be brought upon a specimen or sample collected by him. Of the three parts into which the sample is to be divided, or of the three packages purchased, one must be delivered to the party from whom purchased or to the guarantor. This delivery of the one part or package is evidently for the purpose of notice to the party from whom purchased or the guarantor that proceedings against him under the Act are contemplated. It is not required that

[20]Sec. 3, Page 74. [21]Page 9. [22]Page 84.

the delivery of the one part or package to the party from whom purchased or to the guarantor should be made immediately upon the purchase. Evidently it cannot be delivered to a guarantor in another State or at a distance without considerable delay. It is probable, though not clear from the Regulation, that the one part or package in case of foods or drugs guaranteed under Section 9,[23] should be delivered to the guarantor rather than to the party from whom purchased, as the retailer can hardly be considered as an agent of the guarantor for the purpose of accepting the implied notice of contemplated proceedings. If not delivered to the guarantor, the guarantor should be notified of the collection of the sample and to whom the part or package was delivered. It should perhaps be noted that any one who, pretending to be an agent of the Department of Agriculture, demands samples without offering payment therefor is an impostor and should be treated as such.

The Act contemplates, so far as concerns foods and drugs offered for sale in any State other than that in which they were manufactured or produced, that the sample shall be an unbroken package, or at least be taken from a package which is unbroken prior to the taking of the sample. No prosecution under the Act can be based on a sample taken from a broken package, and it is open to doubt whether a prosecution under the Act of a guarantor under Section 9 can be based on a sample taken from a package broken by the retailer even for the purpose of furnishing a sample. If an original unbroken package is taken as a sample and subsequently opened by an authorized agent of the Department of Agriculture, prosecution of a guarantor may no doubt be based on such sample.

In the District of Columbia and in the territories samples may be taken either from broken or unbroken packages. But for the purpose of prosecution of a guarantor under Section 9,[24], it would seem to be necessary that the sample should be from an original unbroken package.

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18. Collection of Samples—Suggestions.

The fact that samples are collected should be taken as notice that the food or drug of which the sample is taken is suspected by the Department of Agriculture of being adulterated or misbranded, and whether the manufacturer or the dealer who is responsible for the character and branding of such foods or drugs knows such suspicion to be well founded or not, immediate steps should be taken to prepare such defense as can be made. If the food or drug in question is not known or believed to be adulterated or misbranded within the definitions of these terms accepted by the Department of Agriculture, the part or package delivered to the party from whom purchased, or to the guarantor, by the collector, should be at once subjected to examination by a competent chemist if the character of such food or drug is in question, and whether the question is one of adulteration or misbranding, the matter should be submitted to competent legal counsel.

19. Analysis or Examination:

The method of analysis is clearly explained in Regulation 4[25], and the course of proceedings after the completion of analysis or examination of samples is clearly set forth in Regulation 5.[26]

There is no authority under the Act for any publication of the notice to the party from whom a sample was obtained that the examination or analysis shows the provisions of the Act have been violated.

The notice, according to the wording of Section 4,[27] is to be given to the party from whom the sample was obtained. In Regulation 5[26] this is construed to mean notice to the party who is responsible for the adulteration or misbranding, that is, in case of foods or drugs guaranteed as provided for in Section 9,[28] to the guarantor rather than to the retailer from whom the sample was actually purchased.

[25]Page 84. [26]Page 85. [27]Page 75. [28]Page 80.

20. Hearing Before the Secretary of Agriculture.

It is clearly the intent of the Act that the fullest possible opportunity should be given any party alleged to have violated the provisions of the Act, to present in the preliminary proceedings before the Secretary of Agriculture any and all matter of defense which he may have.

Under the provisions of Section 4,[29] the Secretary of Agriculture is required, if it appears that any of the provisions of the Act have been violated, to at once certify the facts to the proper district attorney. At the same time it is probable that the Secretary of Agriculture will be warranted in considering any matter which may be presented in excuse for an unintentional violation of provisions of the Act, and will undoubtedly be warranted in considering arguments as to meaning and intent of provisions of the Act alleged to have been violated, particularly if such provisions of the Act are not entirely clear.

The hearing before the Secretary of Agriculture provided for by this Section is of the utmost importance, as, if at such hearing matters of defense can be so presented as to warrant him in deciding that the examination or analysis of the sample is not correct or that there has been no violation of any provisions of the Act, or that the facts are not such as to require him to certify them to a district attorney, any notice to the public of the fact that the sample appears to show adulteration or misbranding, which in itself may be seriously detrimental, may be avoided.

If the Secretary of Agriculture finds that the facts are such that under the provisions of the Act he must certify them to the proper district attorney and such district attorney institutes proceedings as provided for in Section 5,[30] it will be impossible to avoid some information reaching the public of at least the fact that such proceedings have been instituted.

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21. Proceedings in the Courts.

The precise nature of the proceedings to be brought by the district attorney to whom the Secretary of Agriculture may report any violation of the Act is not clearly set forth in the Act. Presumably it is intended that such district attorney should present the matter to the grand jury for their action.

It should be noted that there is no authority under the Act for instituting any proceedings for violations of the provisions of the Act by any district attorney upon his own initiative, or upon complaint of any purchaser. Proceedings can be instituted only upon the report of the Secretary of Agriculture, and, as provided in Section 4 the Secretary of Agriculture can make such report only after an analysis or examination by Government chemists of samples collected by authorized agents of the Government, and only after notice to the party accused and an opportunity given for hearing. The Act does not permit hasty or ill considered prosecution, or prosecution arising from malice of rivals, and there is nothing in the Act to encourage or reward informers.

22. Publication.

Official publication of the fact that a manufacturer or dealer appears to be or has been adjudged to be responsible for adulterated or misbranded foods or drugs can only be made after judgment rendered upon proceedings brought by a district attorney, the Act in this respect differing from some of the State laws which seem to permit the official publication of the findings of the State chemist without any opportunity being given for a hearing. As above pointed out, however, the fact that proceedings have been brought by the district attorney can hardly be kept from public notice. The publication of the judgment of the court holding the food or drug brought before it to be adulterated or misbranded will be as provided in

paragraph (b) of Regulation 6,[31] by circulars, notices, or bulletins as the Secretary of Agriculture may direct, and will no doubt be so made as to give the fullest possible notice to the public that the food or drug in question is adulterated or misbranded. The effect of such publication will be to practically prevent further sales of such food or drug. Any further sale will be likely to be followed by prosecution for a second offense.

Paragraph (c) of Regulation 6[32] clearly indicates that the publication of the judgment will not be withheld on account of appeal taken.

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CHAPTER III.

ARTICLES TO WHICH THE ACT APPLIES.

23. Articles to Which the Act Applies—Drugs.

The term "drug" is used in the Act in the broadest possible meaning. It includes not only all drugs or medicines, either simple or compounded, which are recognized by any branch of the medical profession as remedies for internal or external use, but all substances or mixtures of substances which are offered to the public as remedies for internal or external use for the treatment or prevention of any disease whatever of man, other animals, poultry, and in general for any living creature, and includes physicians' prescriptions.

The term includes not only what would be generally understood as pharmaceutical preparations, plasters, and proprietary and veterinary medicines, including corn cures, liniments, salves, ointments, and stock foods so-called, but also hair tonics, medicinal soap, cold cream or massage cream, talc powder, perfumes, toilet preparations generally tooth powders and liquid dentrifices. It does not include disinfectants and probably does not include bay rum, face powder, or smelling salts.

The line between foods and drugs is not always clear, particularly as regards substances which, while sometimes used as drugs, are also used as foods or in connection with foods for technical purposes. Such substances when sold or offered for sale for use as medicine will undoubtedly be subject to the requirements of the Act as drugs, but if sold or offered for sale for use as food or for technical purposes, will not be subject to the requirements of the Act. For instance, turpentine or castor oil, if used as a medicine, will be subject to the requirements of the Act; while tur-

pentine if used for paint or varnish or other industrial purpose, or castor oil used for a leather dressing will not be subject to any requirements of the Act.

24. Articles to Which the Act Applies—Foods.

The term "food" as used in the Act expressly includes all articles used for food, drink, confectionery, or condiment by man or other animals, whether simple, mixed or compound. Hay, grain or other food for animals or poultry is undoubtedly included.

The term "food" includes meats and meat products, but the provisions of the Act will not be construed to apply to domestic meats and meat products prepared, transported or sold in interstate or foreign commerce under the Meat Inspection Law, that is meat of cattle, sheep, swine, and goats. *Poultry* and *fish* and other *sea food* of domestic or foreign production is subject to the provisions of this Act. *Imported meats* and *meat products* are subject to the provisions of this Act.

Sugar, salt and *spices* will be subject to the requirement of the Act as foods generally, though if used as medicines or in connection with medicines, they will no doubt be subject to the requirements for drugs if necessary.

Flavoring extracts will be considered foods, but extracts used as medicines will be considered drugs, not foods.

Chewing gum will no doubt be considered as broadly a food and specifically as confectionery.

Coffee and *tea* are considered foods.

Liquors, wines and *beverages* of all kinds are considered foods.

Mineral waters and drinking waters generally are included under the term food.

Milk is, of course, included.

CHAPTER IV.

ADULTERATION.

25. Adulteration.

To the manufacturer of or dealer in food or drug products it is of the utmost importance to clearly understand what is meant by "adulteration" and "misbranding" as used in the Act. Adulteration in its ordinary definition of making impure by admixture of cheaper or inferior ingredients is obviously included, but it is also evident that the term as used in the Act has a broader meaning and includes the use in food or drug products of substances not ordinarily considered adulterants. Broadly speaking, the Act prohibits as adulterated any food or drug product that is below an established or recognized standard of strength, quality, or purity, or that contains any added ingredient which is deleterious or detrimental to health, or which contains any substance specifically prohibited by the Act. To this broad statement there are many exceptions provided for in the Act, and in fact the Act is not to be understood as absolutely prohibiting adulterated foods or drugs even in the ordinary sense of adulteration provided they are plainly and correctly labeled or branded. It does, however, prohibit all adulterated foods or drugs which are not plainly and correctly labeled or branded in accordance with the requirements of the Act, and absolutely prohibits the use of certain substances in foods or drugs, whether specified on the label or not.

26. Adulteration—Drugs—Drug Standards.

In order to determine whether or not an article of food or drug shall be considered to be adulterated within the

meaning of the Act, it is necessary to compare it with some standard definition or description of the article in question, either a generally accepted definition or a definition or description arbitrarily adopted as a standard.

The United States Pharmacopœia or National Formulary is accepted by the Act as correctly defining or describing the strength, quality, and purity of each drug named in it. Unless otherwise plainly stated on its label, any drug sold or offered for sale under or by the name of a drug which is defined or described in the Pharmacopœia or National Formulary must conform to the standard of strength, quality, and purity as determined by the test for such drug therein laid down.

If plainly stated to differ in strength, quality, or purity from the definition or description stated in the Pharmacopœia or National Formulary a drug will not be deemed adulterated provided it is plainly stated on the label what its standard of strength, quality, or purity is, and if in fact it conforms to the statement on the label. With regard to mixtures of substances put up according to a recognized formula, but of half strength, it will be sufficient if the package or bottle is marked "½ Strength."

The first paragraph of Section 7[33] under "drugs" appears to relate to substances and mixtures of substances sold under or by a name recognized in the Pharmacopœia or National Formulary.

The second paragraph[34] relates to drugs generally, whether named in the Pharmacopœia or National Formulary or not, and is clearly intended to include the so-called "Patent" or proprietary medicines. It requires that these as well as all drugs must be in strength and purity up to the professed standard or quality under which they are sold.

In the States the requirements of this Section apply only to drugs in original unbroken packages and not to physicians' prescriptions compounded within the State in which

[33]Page 76. [34]Page 76.

they are sold, but does apply to prescriptions which are shipped out of the State.[35]

In the District of Columbia and the Territories the requirements of this Section apply to drugs in original unbroken packages, and also apply to prescriptions compounded in the District or the Territory.

The United States Pharmacopœia or National Formulary to be taken as determining the standard is prescribed by this section to be that official at the time of investigation. It is understood that the Pharmacopœia is now being or is about to be revised.

27. Adulteration—Foods—Food Standards.

The present Act does not expressly adopt or authorize the establishment of any standards for food products. Under the Agricultural Appropriation Act of March 3, 1903, provision is made for the investigation of the adulteration of foods, condiments, beverages and drugs and also "to enable the Secretary of Agriculture in collaboration with the Association of Official Agricultural Chemists, and such other experts as he may deem necessary, to establish standards of purity for food products and to determine what are regarded as adulteration therein," and in accordance with the provisions of that Act the Department of Agriculture has published as Circular No. 19[36] standards of purity for a large number of food products, and standards for other food products are in preparation.

The standards as published in this circular No. 19,[36] with a few exceptions, such as ice cream in which the percentage of butter fat required (14%), is considered by many manufacturers to be too high, appear to have been generally regarded as correctly describing the various articles of food mentioned in it as manufactured and sold by those who aim to manufacture or to deal in pure food products. While it is doubtful whether the standards established under the authority of the Act of March 3, 1903, are controlling as

[35] F. I. D. 57, Page 122. [36] Page 141.

determining what shall be deemed adulterations of food products under the present Act, such standards are entitled to great weight and will be regarded by the Courts in any proceedings brought under this Act, as persuasive if not authoritative. In so far as these standards conform in their definition of various articles of food to the standard recognized in the trade, the "Trade Description" as it is termed in the British Merchandise Marks Act, they will be regarded as the standards by comparisons with which adulterations are to be determined.

28. Adulteration—Foods—Admixture of Inferior Ingredients.

Under the first and second paragraphs under "food" in Section 7,[37] an article of food is to be deemed adulterated if any substance has been mixed or packed with it so as to reduce, or lower, or injuriously affect its quality or strength, or if any substance has been substituted wholly or in part for it.

The adulteration prohibited by these paragraphs is the common form of adulteration consisting in the admixture or substitution in food products of a cheaper or inferior, though not necessarily or usually harmful, substance, a species of commercial fraud by which the food value of the product is lessened, the object of such adulteration being to reduce the cost to the producer and to enable him by passing it off upon the consumer as of full value, to secure a larger profit than could be made by furnishing an article of standard quality and strength.

Among the food products which have heretofore been found to be particularly liable to this form of adulteration are milk, vinegar, flavoring extracts, confectionery, jellies, jams, preserves, cocoa, honey, butter, molasses, spices, coffee, olive oil, and baking powder.

If the adulteration is carried to the extent of wholly sub-

[37] Page 77.

stituting another substance for the pure article it clearly comes under the prohibition of the first paragraph. If not carried to the extent of complete substitution, it would seem to be covered by either paragraph, the second paragraph appearing to cover such substitution whether or not the quality or strength is reduced, or lowered, or injuriously affected. A claim that the product resulting from the admixture of another substance is better or more wholesome than the pure article is clearly no defense to a charge of violation of these or any other provisions of the Act.

These paragraphs of this Section of the Act are to be read with Section 8[38] relating to misbranding under which mixtures, compounds, imitations or blends are permitted if plainly so labeled.

Construing these paragraphs of Section 7[37] with Section 8,[38] they appear to prohibit the admixture with or substitution in an article of food of any mineral substance, or any inert substance, and to prohibit the admixture of any substance unless the resulting product is plainly stated to be a mixture, compound or blend and the name of the added substance is also stated.

Proprietary foods[39] seem to be excepted from the provisions of these two paragraphs of Section 7 if known under their own distinctive names and not an imitation of or offered for sale under the distinctive name of another article, provided the name be accompanied with a statement of the place of manufacture.

Imitation foods[40] seem to be also excepted from the provisions of these paragraphs of Section 7 if plainly stated to be imitations.

Under Regulation 11,[41] these paragraphs of Section 7 are construed not to prohibit substances properly used in the preparation of food products for clarification or refining and eliminated in the further process of manufacture. This regulation clearly indicates, as has been above pointed out,

[37]Page 77. [38]Page 78. [39]Page 79. [40]Page 79. [41]Page 88.

that the only food or drug that can be made the basis for proceedings under the Act, is the finished product and unless the specimen or sample collected as provided in Regulation 3 is shown on analysis to contain an adulterant or other prohibited substance it cannot be held to be adulterated.

It is not to be understood that these paragraphs or anything in the Act prohibits the addition of water or other proper diluent wherever necessary to reduce an article which is above standard strength to standard strength as, for instance, the addition of water to whiskey which is above proof for the purpose of reducing it to proof as expressly permitted under the Act of March 3, 1897.

29. Adulteration—Foods—Abstraction of Valuable Constituent.

Under the third paragraph[42] under "food" in Section 7, a food product from which a valuable constituent has been wholly or in part abstracted is to be deemed adulterated.

Regulation 26,[43] regarding the sale of waste material, though not designated as bearing upon this paragraph of Section 7, should evidently be read in connection with it. This paragraph seems capable of being read to prohibit the sale of skimmed milk or cheese made from skimmed milk. It is clear from Regulation 26, as well as from the general tenor of Section 8,[44] that nothing in the Act will be construed to prohibit the sale of skimmed milk or any other article from which any valuable constituent has been abstracted provided the skimmed milk or other article is sold or offered for sale for what it is and not as containing all of the constituents originally contained.

The Act does not contemplate or intend to prohibit the sale as food of anything which is wholesome, provided it is not sold under any misrepresentation.

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[42]Page 77. [43]Page 95. [44]Page 78.

30. Adulteration, Foods—Concealment of Damage or Inferiority.

Under the fourth paragraph[45] under "food" in Section 7, any article of food which is damaged or inferior which has been so treated by mixing, coloring, powdering, coating or staining as to conceal the damage or inferiority, is to be deemed adulterated.

(a) *Mixed.* The term "mixed" appears to refer to the mixing of different substances to form what are referred to in Section 8 as mixtures, compounds or blends. The mixing of substances, one of which is damaged or inferior, in such a manner or in such proportions as to conceal such damage or inferiority is clearly prohibited.

(b) *Colored.* The use of coloring matter, whether in itself harmless or not, is prohibited by the paragraph if its effect is to conceal damage or inferiority. The use of coloring matter in food products is not prohibited provided the coloring matter is harmless and is not used to conceal inferiority. The coloring of butter is expressly permitted by the Act of August 2, 1886, and the coloring of cheese is permitted by the Act of June 6, 1896, neither of which Acts are repealed by the present Act.

Harmless vegetable colors may be used for coloring foods and certain of the coal tar or analine colors may be used under the conditions and restrictions prescribed by the Secretary of Agriculture.[46] But neither harmless vegetable colors nor permissible analine colors may be used if their use makes a damaged article appear to be sound or makes an article of inferior quality or character appear to be free from damage or of standard quality or character. The coloring of milk to make it appear richer than it is would be adulteration under this paragraph.

(c). *Powdered.* Under Regulation 12[47] (b) and (c), any article of food which is reduced to a powder to con-

[45]Page 77. [46]Page 89. [47]Page 88.

ceal damage or inferiority in character or quality, will be deemed to be adulterated. Also any article of food to the exterior of which any powdered substance is applied with the effect of concealing damage or inferiority in character or quality will be deemed to be adulterated.

(d.) *Coated.* Under Regulation 12[48] (d), any article of food to the exterior of which is applied a coating of any substance with the result of concealing damage or inferiority will be deemed to be adulterated.

(e). *Stained.* Under Regulation 12[49] (e), any article of food which is exteriorly colored or tinted by the application of any substance with the result of concealing damage or inferiority will be deemed to be adulterated.

This paragraph is clearly so worded that its violation may be determined by examination or analysis of the finished product. The result rather than the intent is the thing to be considered under this paragraph, and the same is true of all of the provisions regarding both adulteration and misbranding. It is the finished product, whether food or drug, and the finished product only, upon which proceedings under the Act can be based.

31. Adulteration—Foods—Colors and Preservatives:

Paragraph five under "food" of Section 7[50] provides that any article of food to which any poisonous or deleterious ingredient which may render it injurious to health has been added, shall be deemed to be adulterated. An exception is made with regard to preservatives applied to the exterior of an article of food in such a way that they do not penetrate the interior or any portion of the interior and must be removed either mechanically or by maceration in water or otherwise before the article to which they are applied can be used as food.

This paragraph applies only to poisonous or deleterious ingredients which are *added to* the food product. Any in-

[48]Page 88. [49]Page 88. [50]Page 77.

gredient, whether poisonous or deleterious or not, which is naturally present in fruit or other food material does not render a food product adulterated. The distinction is a necessary one, otherwise the use of certain fruits, for instance peaches or cranberries, would be prohibited by the Act, since the acids which these and some other fruits contain naturally, would be poisonous or deleterious if used in concentrated form, though in the minute quantities in which they are present in the fruit, they are not harmful to persons in normal health if harmful at all.

This paragraph clearly prohibits the use in food products of colors or preservatives which are poisonous or deleterious, and permits the use of only those colors or preservatives which are harmless. The paragraph does not make any exception as to colors or preservatives which are harmless if used in certain proportions, but are poisonous or deleterious if used in greater proportion, unless this is implied by the words "which may render such article injurious to health."

The Act does not expressly prescribe what colors or preservatives shall be deemed to be poisonous or deleterious, nor does it expressly authorize anyone to determine what colors or preservatives shall be deemed to be poisonous or deleterious. The Act does provide in Section 3[51] that the Secretary of the Treasury, the Secretary of Agriculture and the Secretary of Commerce and Labor shall make rules and regulations for carrying out the provisions of the Act, and acting under this provision the Secretaries have, by Regulation 15,[52] delegated to the Secretary of Agriculture the duty of determining the wholesomeness of colors, preservatives and other substances which are added to foods, with the proviso that the findings of the Secretary of Agriculture when approved by the Secretary of the Treasury and the Secretary of Commerce and Labor shall become a part of the Regulations. Any determination by the Secretary of

[51]Page 74. [52]Page 89.

Agriculture of the wholesomeness of colors, preservatives and other substances which are added to foods, whether approved by the Secretary of the Treasury and the Secretary of Commerce and Labor or not, while no doubt entitled to great weight, is not binding upon the courts. Manufacturers of food products who use only the colors or preservatives which are approved by the Secretary of Agriculture, will avoid any risk of prosecution under the Act. Those who choose to use colors or preservatives not authorized by the Secretary of Agriculture take the chances of prosecution, but if able to show to the satisfaction of the court that the colors or preservatives are not in fact poisonous or deleterious, will not be held guilty of violation of the provisions of the Act so far as their use of such colors or preservatives is concerned.

In Regulation 39 of the Regulations governing the Meat Inspection of the U. S. Department of Agriculture, the preservatives permitted to be used in meats or meat products are "common salt, sugar, wood smoke, vinegar, pure spices, and, pending further inquiry, saltpeter." No colors may be used in meats or meat food products except such as may be approved by the Secretary of Agriculture.

Under the present Act the preservatives authorized to be used in meats and meat food products will be permitted to be used in food products, and certain other preservatives will be permitted under prescribed conditions and in prescribed quantities or proportion.

It is probable that benzoate of soda will be permitted to be used for a limited term of years in quantities not exceeding 1/10 of 1 per cent in catsup and perhaps a few other foods, and that the use of sulphurous acid for bleaching purposes in the manufacture of syrup and dried fruits will also be permitted, provided the sulphurous acid remaining in the syrup or the dried fruits does not exceed a prescribed percentage.

It is probable that a few of the analine colors claimed to be harmless will be permitted to be used for at least a lim-

ited period, but particular care will be required to be taken by the user of such permitted analine colors to be certain that such colors are free from deleterious matter and have been proved to be in fact harmless.

In case any of the preservatives which are permitted to be used, other than those permitted under the Meat Inspection Law, or any of the permitted analine colors, are used, the fact of their use and probably the proportion in which they are used will be required to be stated on the label.

Definite rulings on the matter of preservatives and colors have not yet been issued.

Under the exception in paragraph 5[53] permitting the use of external preservatives, rice may be finished by coating with one-thousandth part glucose and one three-thousandth part talc, provided each pocket of rice is provided with a tag stating the fact with direction to remove the coating by washing, together with the name of the manufacturer and his place of business. Paraffin, not being removable by washing, may not be used in milling rice. Boric acid, even if applied externally as a preservative, will not be permitted, it being considered that it cannot be so used without more or less permeation of the food article to which it is applied.

32. Adulteration—Foods—Prohibited Colors and Preservatives.

Preservatives and colors other than those expressly permitted cannot be used in food products without rendering the products liable to be held adulterated. Among the preservatives or other substances deemed to be poisonous or deleterious and thus, in effect, forbidden to be added to food products, may be mentioned:

Benzoic Acid (except as above page 30).
Boric Acid.
Formaldehyde.

[53]Page 77.

Glycogen.
Saccharine.
Salycilic Acid.
Sodium Sulphate.
Sulphate of Copper.

All mineral colors and all analine colors other than those expressly permitted are prohibited.

33. Adulteration—Foods—Effect of Rulings.

It should be distinctly understood that the rulings of the Secretary of Agriculture in the matter of colors and preservatives are not made as absolutely decisive upon the questions ruled on. The final determination upon these questions rests with the courts. The Secretary of Agriculture, however, as regards the enforcement of the provisions of the Act occupies the double position of complainant and magistrate before whom the complaint is preliminarily heard with power to hold the accused for trial by a United States court. It obviously follows that with regard to the use of particular colors or preservatives as well as with regard to other matters provided for in the Act, if the Secretary of Agriculture holds that such colors or preservatives may be used there will be no complaint and no proceedings before the court. On the other hand, if the ruling of the Secretary of Agriculture does not permit the use of the color or preservative in question he may institute proceedings and hold the accused for trial by the courts. Unless a manufacturer is confident that the holdings of the courts will be contrary to the rulings of the Secretary of Agriculture, it will be advisable to accept his rulings.

34. Adulteration—Foods—Character of Raw Materials.

Under the sixth paragraph,[54] under "food" in Section 7, a food product will be deemed to be adulterated if it con-

[54]Page 77; Page 143.

sists in whole or in part of a filthy, decomposed or putrid animal or vegetable substance or any portion of an animal unfit for food, or if it is the product of a diseased animal or one that has died other than by slaughter.

The language of the paragraph is clear and positive. There is no doubt that proceedings should be and will be brought against anyone violating its provisions. It is not, however, clear that proceedings can be brought even under this paragraph unless the sample or specimen collected in the regular way shows on examination or analysis that the provisions of the paragraph have been violated. It is, however, probable that any product made in violation of this paragraph will show upon examination or analysis that it is composed in whole or in part of prohibited material as such material can hardly be concealed unless by mixing, powdering, coating or staining, in which case the product will violate the fourth paragraph.[55]

This paragraph undoubtedly covers milk which is unfit for use because of filth or which is the product of diseased cows, and probably also covers mineral or other drinking water which is unfit for use because of the presence of filth or decomposed animal or vegetable substance, as well, of course, covering any other food product unfit for use because of filth.

35. Adulteration—Foods—Confectionery.

All of the above considered provisions respecting foods apply also to confectionery. In addition, the presence in confectionery of certain substances, some of which may be used in other food products, will cause it to be deemed adulterated.

The term "confectionery" is not defined in the Act or in the Food Standard Bulletin of the Department of Agriculture, circular No. 19.[56]

In the bulletin referred to, "Candy" is defined as "A

[55]Page 77. [56]Page 148.

product made from a saccharine substance or substances, with or without the addition of harmless coloring, flavoring or filling materials, and contains no terra alba, barytes, talc, chrome yellow, or other mineral substances or poisonous color or flavors or other ingredients deleterious or detrimental to health, or any vinous, malt or spirituous liquors or compounds or nacotic drug."

Probably chewing gum and ice cream will both be subject to the provisions regarding confectionery.

This section of the Act clearly prohibits the use in confectionery of any mineral substance whatever, including paraffin and all mineral colors. Whether coal tar or analine colors and flavors are mineral substances seems to be a controverted question, but the coal tar or analine colors held by the Secretary of Agriculture to be permissible may be used in confectionery under the conditions prescribed and for the period therein stated.

Vegetable colors and flavors may be used in confectionery provided they are harmless.

Saccharine may not be used in confectionery.

Gelatin if free from bisulphates or other deleterious ingredients may be used in confectionery.

Glucose containing bisulphates may not be used.

Bleachers or hardeners containing bisulphates may not be used in confectionery.

Shellac may be used in glossing candy provided the alcohol in which it is dissolved is so completely evaporated as to leave no trace on or in the candy.

Vaseline or other harmless fats and oils may be used in finishing confectionery.

In *chewing gum* paraffin or chicle may undoubtedly be used provided the soluble ingredients, sugar, color, flavor, etc., conform to the requirements of the Act.

No *vinous, malt, or spirituous liquors or compound* may be used in confectionery. This does not exclude the use of flavoring extracts or the use of vinous, malt or spirit-

uous liquors or compounds for flavoring merely, provided there is no trace of alcohol in the finished product.

No *drug of a narcotic nature* may be used in confectionery. This prohibits not only all of the drugs mentioned in Section 8[57] and their derivatives as stated in Regulation 28 (f)[58] but all other drugs of a narcotic nature.

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[57]Page 78. [58]Page 96.

CHAPTER V.

MISBRANDING.

36. Misbranding in General.

The provisions contained in Section 8[59] are the most important provisions of the Act. The Act prohibits adulteration and defines in Section 7 what shall be deemed adulteration, but there is nothing in Section 7[60] or in any Section of the Act which requires either foods or drugs to conform to any standard of strength, quality or purity, provided the food or drugs are sold or offered for sale for what they really are, and provided, of course, that they are not of a character which renders them unfit for use.

The main purpose of the Act is not necessarily to secure uniformity in food or drug products or to prevent the sale of substandard or even inferior foods or drugs, but to prevent the passing off upon the public of substandard or inferior foods or drugs labeled or branded or otherwise represented to be of standard quality, strength or purity.

Perhaps the best test of "misbranding" so far at least as concerns foods and drugs not subject to specific provisions of the Act, is the test prescribed in the Trademark Act of February 20, 1905, for determining the registrability of a trademark. In order to be registrable, a trademark must not so closely resemble a trademark owned or in use by another and applied to merchandise of the same descriptive properties "as to be likely to cause confusion or mistake in the mind of the public or to deceive purchasers."

Foods or drugs which bear a label or brand which correctly states the contents of the package in such a way as not "to be likely to cause confusion or mistake in the mind

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[59]Page 78. [60]Page 76.

of the public or to deceive purchasers" cannot be held to be misbranded.

37. Misbranding—False Trade Description.

The first paragraph of Section 8[61] appears to prohibit, in connection with foods or drugs, the use of what is termed in the British Merchandise Marks Act of 1887, a "false trade description." In view of the fact that in general purpose and to a considerable extent in language, the present Act is closely analogous to the Merchandise Marks Act, it is not unlikely that the numerous decisions of the English courts on the Merchandise Marks Act, while in no sense controlling, will be entitled to considerable weight in the construction and application of the present Act by the United States courts.

Under the Merchandise Marks Act, 1887, every person is subject to the provisions of the Act who

> (d) applies any false trade description to goods,

and the Act defines "trade description" as follows:

> The expression "trade description" means any description, statement, or other indication, direct or indirect.
>
> (a) as to the number, gauge, or weight of any goods, or
>
> (b) as to the place or country in which any goods were made or produced, or
>
> (c) as to the mode of manufacturing or producing any goods, or
>
> (d) as to the material of which any goods are composed, or
>
> (e) as to any goods being the subject of an existing patent privilege or copyright,
>
> and the use of any figure, word, or mark which, according to the custom of the trade is commonly taken to be an indication of any of the above matters, shall be deemed to be a trade description

[61] Page 78.

within the meaning of the Act. The expression "False Trade Description" means a trade description which is false in a material respect as regards the goods to which it is applied, and includes every alteration of a trade description, whether by way of addition, effacement, or otherwise, where that alteration makes the description false in a material respect, and the fact that a trade description is a trademark, or part of a trademark, shall not prevent such trade description being a false description within the meaning of this Act.

* * * * * * * * * *

The provisions of this Act respecting the application of a false description to goods shall extend to the application to goods of any such figures, words, or marks, or arrangement or combination thereof, whether including a trademark or not, as are reasonably calculated to lead persons to believe that the goods are the manufacture or merchandise of some person other than the person whose manufacture or merchandise they really are.

The Merchandise Marks Act provides that its provisions respecting "false trade description" shall extend to the application to goods, of a false name or initials, which it defines as meaning

any name or initials of a person which

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(c) are either those of a fictitious person or of some person not *bona fide* carrying on business in connection with such goods.

It seems to be clear that the first paragraph of Section 8 of the present Act is intended to prohibit the use of the "false trade description" and false name or initials of the merchandise, and is perhaps capable of being construed to also prohibit statements, designs or devices which would not be within these terms of the British Act.

It should be noted that, while the Merchandise Marks Act provides that it shall be a sufficient defense if the defendant

charged with applying a false trade description to goods shows

(b) that he took reasonable precautions against committing the offense charged, and

(c) that he had at the time of the commission of the alleged offense, no reason to suspect the genuineness of the trademark or trade description.

The present Act does not distinguish between wilful misbranding and unintentional misbranding. If the label or brand on the sample or specimen collected as provided for is false or misleading in any particular, the person responsible for such misbranding is liable under the Act without regard to the question of intent.

38. Misbranding—Prior U. S. Statutes.

The Act of August 14, 1876, makes the counterfeiting of a registered trademark and the selling or offering for sale of goods bearing a fraudulent trademark an offense punishable by fine or imprisonment. The Act then in force providing for the registration of trademarks was, in 1879, held unconstitutional by the Supreme Court, because it was not limited to trademarks used in interstate or foreign commerce, and it has been generally considered that the Act of August 14, 1876, became obsolete and is now without force or effect. While Trademark Registration Acts were subsequently adopted, in 1881 and in 1905, there has been up to the present time no re-enactment of a law providing for the punishment of counterfeiting trademarks. The Act of July 1, 1902, prohibits, under penalty, the introduction into any State, or Territory, or the District of Columbia, from any other State, Territory, or the District of Columbia, of any dairy or food products falsely labeled or branded as to the State or Territory in which they are made, produced or grown. The marking or branding of oleomargarine, butterine, renovated butter, filled cheese, mixed flour and in certain respects of distilled and fermented liquors are regu-

lated by Statute, and the misbranding of imported foods or drugs is prohibited by Statute. But the present Act is the first Act of general application to all food and drug products, whatever their origin, which prohibits misbranding.

39. Misbranding—False or Misleading Statement—Design or Device.

The first paragraph of Section 8,[62] applying generally to both food and drug products, prohibits the use on the package or label of anything whatever which is calculated to deceive or mislead a possible purchaser as to the character or quality of the article to which it is applied, or as to the source from which it is derived. A purchaser may be mislead by pictorial matter as much as by direct statement in words, and may be as much deceived by omission to state facts of which he should be informed as by absolutely false statements. Food products which are prepared according to usual and generally understood processes and in which only the ordinary preservatives such as sugar, vinegar, salt, spices, or wood smoke are used need no statement to explain what they are nor is any explanation needed when food products contain only the color natural to them. But in the case of food products in which preservatives not commonly used and with which the general purchaser is not likely to be familiar, are used, or in which artificial colors are used, the purchaser has a right to know what preservatives or colors are used, and omission of such statement as to preservatives or colors as may be necessary to enable him to correctly inform himself as to the character and quality of the article offered him, is calculated to deceive and should not be permitted, and is not intended to be permitted by Section 8[62] of the Act. By necessary implication the first paragraph of this Section warrants the requirement that artificial color or preservatives other than those usually employed shall be stated on the label and wherever material to a proper understanding of the character and quality of

[62]Page 78.

the product, the quantity or proportion of such color or preservative should be stated.

It is not usually of material importance to the purchaser that he be informed of the locality of origin of the article offered him or of the name of the manufacturer. A standard drug product or medicinal preparation is hardly likely to be modified in character by climatic or other local conditions, or by a particular manufacturer, and the same is generally true of food products and it is not, therefore, material that the locality of origin or the name of the manufacturer should be stated on the label. But if either is stated it is fairly to be assumed that in the particular case the locality of origin or the name of the manufacturer has a distinct bearing upon the character or quality of the product, and if stated should be correctly stated.

Pictorial matter on a label may be calculated to convey a false impression as to the character or quality of the contents of the package as, for instance, if pictures of honey bees or beehives are placed upon packages containing imitation or adulterated honey, or if pictures of maple leaves or maple sugar camps are placed upon syrups or sugars which are not pure maple, or if pictures of coffee plants or coffee plantations are placed on preparations that are not pure coffee. All such pictorial representations, designs or devices are clearly prohibited under this paragraph of Section 8.[63]

With regard to drugs, particularly proprietary remedies, the rulings of the Department of Agriculture are likely to be strict as to what constitutes a false or misleading statement as to the quality. A statement on a package or label that the preparation is a "cure" for the disease for the treatment of which it is offered, is more than likely to be considered misbranding, particularly if the diseases which the preparation is stated to "cure" are generally considered to be incurable. The use of the words "Remedy for" instead of "cure" is understood to be permissible.

[63]Page 78.

Statements on packages or labels which assert for the preparation curative properties beyond what is warranted by actual fact are likely to be deemed false and misleading.

40. Misbranding—Trademarks.

The fact that a design or device used on a package or label has been registered as a trademark is not sufficient to warrant its use in any manner which is calculated to deceive. It is well settled by numerous decisions that the courts will not protect trademarks or labels, whether registered or not, which are deceptive as to the character or quality of the goods on which they are used.

The language of this paragraph is clearly capable of being construed to prohibit the use on a package or label of a "design" or "device" which is a counterfeit, copy or colorable imitation of a trademark which is recognized in the trade as distinguishing the goods of another manufacturer or dealer. The importance to the public of prohibiting a dishonest manufacturer or dealer from passing off his goods, probably inferior, as goods which are well known to be of superior character or quality, by so marking them that the purchaser will be deceived, is not less than the importance of prohibiting the use of false indications of origin

41. Misbranding—Name of Manufacturer—Fictitious Names.

The name of the manufacturer need not be stated on the label. If stated at all it must be correctly stated. If the name of any person, firm, or corporation not actually the manufacturer appears on a label without words indicating that such name is not to be understood as the name of the manufacturer, the goods may be held to be misbranded. The name of the wholesaler, jobber, agent, importer, distributor or retailer may appear on the label, provided it is accompanied by words like "packed for," "distributed by," "importer," "agent," which will indicate that the name which

appears is not to be understood as purporting to be the name of the manufacturer. There is nothing in the Act which is intended to restrict the use of private brands or to require the name of the actual manufacturer or packer to appear on the label provided the name of the owner of the private brand, who is not the manufacturer or packer, is not so used as to falsely indicate that he is the manufacturer or packer.

While, as regards the name of the manufacturer, the Act does not expressly prohibit the use of fictitious names on labels, and while fictitious names are not expressly mentioned in the Rules and Regulations, there is no doubt that the Department of Agriculture will construe the language of the Act to prohibit the use, on foods or drugs, of any fictitious name which purports to be the name of the manufacturer.

The language of the Act is clearly capable of this construction and there is no doubt that in case of certain food products, particularly olive oil, fictitious names and false indications of origin have been used to pass off upon the public inferior goods. It is not clear that the use of fictitious names by packers of canned goods in this country to indicate a grade of their goods inferior to the goods put out under their proper names, has actually deceived the public. But whether actually deceptive or not, it is clear that the use of fictitious names on any food or drug products will not be permitted, and, as it is probable that the Department of Agriculture would be sustained in its position by the courts, it is advisable that the use of fictitious names on food or drug products should be discontinued.

It should, however, be understood that a name which a manufacturer or packer has the right to use as successor or assignee is not to be considered a fictitious name.

42. Misbranding—False Indication of Origin.

There is nothing in the Act which requires the name of the State, Territory or country in which an article of

food or drug is manufactured or produced, to be stated on the package or on the label, except in case of mixtures or compounds having a distinctive name. If stated, the name of the State, Territory or country is required to be correctly stated. In many foreign countries certain localities have become noted for the production of certain food products which are peculiarly dependent for their character upon the character of the soil or climatic conditions, and the same is true of certain localities in the United States. Many of the States are noted in the matter of food products for some one or more products which, while perhaps capable of being produced in other States, are at their best in that State. Vermont Maple Syrup, Maine Canned Corn, New York Canned Fruits, Delaware Peaches, Baltimore Oysters, Cape Cod Cranberries, Smithfield Hams, Kentucky Whiskey, Elgin Butter, Indian River Oranges, are all food products which by reason of the efforts of the producers in the localities indicated are generally recognized on the market as distinctive products commanding the higher prices. In the wine producing countries of Europe names of certain localities like Champagne, Cognac, Burgundy, Port, Tokay, Moselle and others, applied to products characteristic of the particular locality, indicate, when properly used, products which are of the highest excellence and command the highest prices. So also Java or Mocha for coffee.

Such geographical names are in the nature of trademarks differing from trademarks in the ordinary sense in that the right to use them belongs not to an individual but to the producers located within a certain region. By students of trademark law they are termed "Regional Marks" or "Collective Marks," and in many foreign countries their use is protected by law as strictly as is the use of individual trademarks, such protection being afforded both as a protection to the public against deception and as a protection of a recognized property right in the mark. The protection of these regional marks, collective marks or indications of origin as they are variously termed has been frequently the

subject of treaty arrangements between foreign countries. France, Great Britain, Portugal, Spain, Switzerland, Brazil and Tunis are parties to an agreement concluded at Madrid April 14, 1891, having for its express purpose the suppression of false indications of origin.

On account of the fact that certain geographical names used by the producers within certain regions to indicate the origin of their products have been so extensively used by imitators that they are, sometimes at least, understood as indicating a type or style of product without regard to its source, it is provided in paragraph (c) of Regulation 19[64] that the use of such geographical names will not be deemed misbranding if the State or Territory where the article is produced is stated, and if the geographical name is used to indicate style, type or brand. "Tokay style, California," "Champagne style, New York," or like markings will probably be permitted in cases of wines which resemble the genuine Tokay or the genuine Champagne.

Where a geographical name indicates locality of origin only, and is not understood as indicating a type or style, its use on an article of food or drug not produced in the region indicated will be misbranding. The name Java on coffee will no doubt be deemed a misbranding if used upon Brazilian coffee or on any coffee not imported from Java or at least from the region in which Java is located.

Geographical names which do not indicate the origin of the product to which they are applied but are used merely as indicating a species or variety, such names for instance as Delaware grapes, Concord grapes, and the like, are properly used when applied to the products known by these names wherever grown or produced.

The wording of the first paragraph of Section 8[65] would seem to require a manufacturer or packer having plants located in several States and using on his labels the address of his main office, to indicate on goods packed in a State

[64] Page 93. [65] Page 78.

other than in which his main office is located, the name of the State in which they were actually manufactured or packed. It is clear from paragraph (b) of Regulation 18[65] that such requirement may be made if deemed necessary by the Secretary of Agriculture to prevent deception. The enforcement of such a requirement generally is probably unnecessary and it is not likely to be enforced, unless its non-enforcement is taken advantage of to actually deceive the public.

43. Misbranding—General Requirements as to Label —Articles Without a Label:

There is nothing in the Act which requires food or drug products to be branded or labeled unless they contain certain specified substances or are otherwise of a character which would render them liable to be prohibited as adulterated without some statement of character or quality. But the omission of a label or brand will not avoid liability under the Act if the article without a label sold or offered for sale is an imitation of or is offered for sale under the name of another article. Regulation 22,[66] which expressly prohibits selling or offering for sale an unlabeled article of food or drug, if an imitation of or sold under the name of another article, is clearly warranted by the provisions of Section 8.[67]

There is nothing in the Act which requires the name of the article to be placed on the label or on the package, but if a name is used it must be the true name. If a drug which is recognized by name in the U. S. Pharmacopœia or National Formulary it must, if it bear any name, bear the name thus recognized. The common English name may be used if preferred. For instance, Magnesium Sulphate may be labeled Epsom Salts. A food product if it is commonly known to the trade must, if it bear any name, bear the name by which it is commonly known.

[65]Page 92. [66]Page 94. [67]Page 78.

The label need not bear the name of the manufacturer or the name of the locality in which it was produced except in certain cases specifically provided for in the Act, but if either is used it must be the correct name.

44. Misbranding—Form of Label:

With regard to the form or character and appearance of the label upon food and drug products not specifically provided for in the Act no requirement is made. So far as paragraph (b) of Regulation 17[68] seems to require a particular arrangement of the matter on the label on food and drug products not specifically provided for in subsequent paragraphs of this Section, it is to be taken, in view of decisions of the Secretary of Agriculture, F. I. D. 52,[69] January 18, 1907, as suggestive rather than directory.

The labels now in use on canned goods and most other food products which are put up in packages may continue to be used without change provided they contain no false or misleading statement, design or device. The same is true of the labels now in use on the drugs which are sold under names recognized in the Pharmacopœia or National Formulary. Such articles, both of foods and drugs, are generally free from adulteration and contain no objectionable color or preservative and do not bear any false statement as to who manufactured them or where they were manufactured.

45. Misbranding—Drugs.

The first paragraph under "drugs" in Section 8[70] provides that an article shall be deemed misbranded if it be an imitation of another article or offered for sale under the name of another article. The prohibition is clear and definite.

No drug which is labeled as being other than it really is will be permitted to be passed off upon the public so far as the Government has the constitutional power to pre-

[68]Page 90. [69]Page 116. [70]Page 78.

vent. It does not appear that an imitation of a drug is permitted even if plainly stated to be an imitation. So far as drugs, in the ordinary sense, that is simple or compounded drugs, are concerned there can be no such thing as an imitation. An article either is or is not the drug which it purports to be. As regards medicines in the ordinary sense, that is compounded drugs, there would seem to be no reason for permitting imitations even if plainly stated to be such.

The name applied to a drug must be the name under which it is recognized in the Pharmacopœia or National Formulary, or if recognized under two names as for instance —Epsom Salts and Magesium Sulphate—either may be used. If not recognized in the Pharmacopœia or National Formulary the name must be the trade designation applied to the article. A drug or an article purporting to be a drug will not be permitted to be passed off upon the public as being a drug named in the Pharmacopœia or National Formulary when it is not, or as a drug known in the trade under a certain name or trade description when it is not what it purports to be.

It would seem also that a preparation purporting to be a medicinal preparation known to the trade under a distinctive trademark should be deemed to be misbranded if the package or label bears any imitation of such distinctive trademark.

46. Misbranding—Drugs—Refilling.

The first part of the second paragraph under "drugs" in Section 8[71] prohibits the refilling of packages from which the original contents have been removed either wholly or in part. This is, of course, to be understood as meaning refilling for purposes of sale and not to prohibit any use to which a bottle or carton might be put after its original contents have been removed and the label or brand removed or destroyed.

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[71] Page 78.

So far as concerns the District of Columbia and the Territories it is not material whether a refilled package is to be considered an original unbroken package or not, as in either case the refilling is a violation of the provisions of the Act. So far as concerns the States it is doubtful whether the refilling of an original package and delivering it or offering to deliver it to another person, within the State in which the package was refilled, can be punished under the Act. It would seem that in such case the refilling would be a matter to be dealt with under the laws of the State in which the package was refilled. If the refilled package is shipped out of the State in which it was refilled, it may probably be treated as an original unbroken package.

47. Misbranding—Drugs—Substances Required to Be Named.

In the requirement contained in the second paragraph under "drugs" in Section 8[72] that the quantity or proportion of alcohol or other substances named in this paragraph or any derivative or preparation of any such substances, contained in any drug shall be stated on the label, the term "drug" is used in the broad sense to include all medicines and drug preparations whether recognized by name in the Pharmacopœia or National Formulary or not. The requirement is undoubtedly intended to apply particularly to the so-called "Patent" medicines or proprietary remedies.

The requirement applies to veterinary medicines and stock foods as well as to all preparations having or purporting to have medicinal properties for either external or internal use for the treatment or prevention of disease in man or any living creature.

The requirement applies to physicians' prescriptions if compounded in the District of Columbia or in a Territory whether shipped out of the District or Territory or not, and also to physicians' prescriptions compounded in a State and shipped out of the State.[73]

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[72]Page 78. [73]F. I. D. 57, Page 122.

The requirement, so far as concerns alcohol, does not apply to flavoring extracts, these being classed as foods.[74]

The substances required to be mentioned on the label are named in the second paragraph[75] of this Section of the Act. The derivatives or preparations of the substances named in the Act are stated in paragraph (f) of Regulation 28.[76]

48. Misbranding—Drugs—Statement of Quantity or Proportion.

The quantity or proportion of the substances required to be named on the label is the quantity or proportion contained in the finished product. Any substance used in the preparation of a drug or medicine which is eliminated in the process of preparation need not be mentioned on the label.[77] It is the finished product only from which samples or specimens can be taken for analysis by the Department of Agriculture, and the proceedings under the Act can be based only upon the analysis or examination of such samples or specimens.

If a substance named in the Act or a derivative of such substance is present in the finished product only as a mere trace, it probably need not be mentioned on the label. If present in any material proportion or any quantity sufficient to enable its presence to be determined with certainty by analysis or examination, it must be mentioned on the label.

Under Regulation 30,[78] the quantity or proportion in case of alcohol must be stated by percentage of volume in the finished product, while in case of any of the other substances required to be named the quantity or proportion must be stated in grains or minims per fluid ounce or miligrams per gram or per cubic centimeter or grams or cubic centimeters per kilogram or per liter. The Regulation seems to require, even in case of medicines put up in tablets, powders, or capsules, that the quantity or proportion be stated in grains or minims per ounce (or as specified if the metric system

[74] F. I. D. 47, Page 113.
[75] Page 78.
[76] Page 97.
[77] Page 88
[78] Page 98.

is used). It would convey to the purchaser the information required to be given by the Act if, in the case of medicines put up in such form, the quantity of the substance required to be named contained in each powder, tablet or capsule should be stated. Such statement of quantity would seem to be both within the spirit and the letter of the Act and it is not probable that medicines put up in such forms will be deemed misbranded, if the label states correctly the quantity of the substances required to be named which is contained in each tablet, powder or capsule.

The quantity or proportion required to be named should be stated as correctly as possible, but should not be understated.[79] Reasonable variation from the stated quantity or proportion is permissible provided the average quantity or proportion is correctly stated.[79]

49. Misbranding—Drugs. Alcohol—Wood Alcohol.

Grain or ethyl alcohol is the only alcohol required to be named on the label.[80]

Wood alcohol or other substances chemically known as alcohols, such as fusel oil, if present, need not be named on the label.

Under paragraph (a) of Regulation 28,[81] the use of wood alcohol or any alcohol other than grain or ethyl alcohol is not permissible in the manufacture of drugs except as specified in the Pharmacopœia. Under this Regulation the use of wood alcohol, or denatured alcohol in hair tonics, liniments or other preparations for external or internal use, is prohibited.

50. Misbranding—Drugs—Form of Statement of Substances Required to be Named.

Under paragraph (b) of Regulation 28,[82] the names of the substances required to be named, and the quantity or proportion is required to be printed in type not smaller

[79]Page 96. [80]Page 96. [81]Page 96. [82]Page 96.

that 8 point (brevier) caps, unless the package is so small as not to permit the use of such type, in which case a smaller type may be used.

Under paragraph (b) of Regulation 17[83] the names of the substances required to be named must appear upon the principal label without intervening descriptive or explanatory reading matter, that is, immediately following the name of the drug product. In view of Decision of the Secretary of Agriculture No. 52,[84] January 18, 1907, it would seem that this arrangement is suggested and desired rather than insisted upon. Statements of the reason for using alcohol or other substance required to be named should be clearly separated from the statement of the substances required to be named and their quantities or proportions.

In stating on the label the quantity or proportion of the substances required to be named, the names by which these substances are designated in the Act should be used.[85] The Department of Agriculture considers it desirable that when preparations of the substances required to be named are used, the word or words used in the Act should constitute the first part of the name of the product. For instance, "Opium, Tincture of" or "Cannabis Indica, Extract of" should be used instead of "Tincture of Opium," or "Extract of Cannabis Indica."

It seems clear from the decisions so far given out by the Department of Agriculture that the Act will be construed to require that the substances required to be named must be distinguished by their usual and commonly understood names.[86] It is apparent that the Department construes the Act to require that the information as to substances contained in medicinal preparations should be given in language which will be readily understood by the purchasing public. The use of a chemical formula or a chemical name to designate a substance which has a name under which it is generally known to the public, is not considered by the Department to be a compliance with the requirements of the Act.

[83]Page 90. [84]Page 116. [85]F. I. D. 55, Page 119. [86]F. I. D. 56, Page 120.

51. Misbranding — Drugs — Supplemental Label, Stamp or Paster.

Under paragraph (i) of Regulation 17[87] labels now on hand may be used without change until October 1, 1907, provided that any statement thereon as to the character of the contents contrary to the provisions of the Act, is corrected by a supplemental label, stamp or paster.

While not expressly so stated it is probable that such supplemental label, stamp or paster will be required to conform in size of type used with the regulations respecting the principal label.

52. Misbranding—Drugs—Formula.

The Act does not require the formula of any drug product, medicine or proprietary remedy to be stated on the label. A statement of the formula on the label will not be considered to be the equivalent of the statement as to the substances required to be named, and, as definitely stated in Decision of the Secretary of Agriculture No. 53,[88] January 28, 1907, all drug products and their labels must conform to the Act whether the formula is or is not given on the label.[88] The formula, if given, must be correctly stated; otherwise it will be considered a false or misleading statement.

53. Misbranding—Foods—Imitations.

The first paragraph under "food" in Section 8[89] prohibits the sale of an imitation of another article. So far as concerns imitations of food products which are known by a distinctive name which is the property of another, such as certain arbitrary or fanciful names used as trademarks, this prohibition is absolute. So far as concerns imitations of food products known under general names such as coffee, maple syrup, chocolate creams, vanilla extract and whiskey, the prohibition is modified by the provision in a succeeding paragraph of this Section, which permits such imitations to be

[87]Page 91. [88]F. I. D. 53, Page 118. [89]Page 78.

sold, provided they are labeled, branded or tagged so as to plainly indicate that they are imitations.

54. Misbranding—Foods—Distinctive Names.

"Distinctive name" in this paragraph means the trade description by which an article is known to the public. It includes a generic name by which an article is known such as Coffee, Flour, Tea, Sugar, Vanilla and Chocolate and also includes arbitrary or fanciful names applied by an individual manufacturer to the particular goods which he puts upon the market, in other words trademark names. This paragraph clearly prohibits the use upon any article of food of the name "Coffee" if the article is not coffee, or "Maple Syrup" if the article is not maple syrup, or "Olive Oil" if it is not olive oil, and also clearly prohibits the use upon a package of coffee of a name which indicates that is is coffee of a particular known brand, if it is not of that brand.

Under paragraph (d) of Regulation 19[91] the use of a foreign name which is recognized as distinctive of a product of a foreign country is prohibited upon an article of domestic origin except as an indication of the type or style of quality or manufacture, and then only when so qualified that it cannot be offered for sale under the name of a foreign article. This applies directly to the labeling of domestic cheese as "Roquefort," "Camembert," "Stilton," as well as to other articles of food, wines or liquors which are sold under foreign names which are understood by the public to designate a distinctively foreign product. Domestic cheese which is properly described as of the type or style of Roquefort cheese may be labeled as "Roquefort type," or "Roquefort style," but if so labeled the word "type" or "style" will be required to be plainly printed in type sufficiently large to prevent its being overlooked by the purchaser.

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[90]Page 78. [91]Page 93.

55. Misbranding—Foods—Waste Materials.

There is nothing in the Act which prohibits the selling or offering for sale of any product which has any food value whatever, provided it is not made of materials which are unfit for food and contains no added substance which is considered to be deleterious, and provided it is not misrepresented either by statements on the labels or otherwise. Inferior fruit or other food material, trimmings, pieces, stems or the like, may be entirely wholesome and there is no doubt a demand for such products from those who cannot pay for the standard quality of goods, but it is important that such goods should not be passed off as better than they really are. It is therefore required under Regulation 26[92] that such goods be marked "pieces," "stems," "trimmings," or by some similar appellation.

56. Misbranding — Foods — Deceptive Labeling or Branding—Refilling.

The first part of the second paragraph under "food" in Section 8,[93] taken with the first paragraph under "foods" and the introductory paragraph of the Section, would seem to cover every possible case of so marking or labeling food products as to deceive the public as to their character, quality, or origin. This second paragraph specifically prohibits so marking the article of food as to indicate that it is a foreign product when it is not. A label in a foreign language, a foreign name as the manufacturer's or producer's name or the name of a foreign locality as the locality of origin, if used upon food products of domestic origin in such a way as to cause a purchaser to believe it to be of foreign origin, would clearly be a violation of the provisions of the Act. There is nothing in the Act which prohibits the use of a label in a language other than English additional to a principal label in English, when used on products sold or offered for sale in localities in which a language other than

[92] Page 95. [93] Page 78.

English is extensively used. Under paragraph (c) of Regulation 17[94] a foreign label appears to be expressly permitted in the language of the country where the drug or food is produced or manufactured.

The first part of the second paragraph under "food" also prohibits the refilling of packages the original contents of which have been removed in whole or in part. This applies only to the refilling of packages which still retain their original labels or brands, for the purpose of passing off the refilled packages as original packages. It would be a violation of the provisions of this paragraph, in the District of Columbia or in the Territories, for a retail dealer in liquors or a bartender to refill, in whole or in part, a whiskey bottle bearing a distinctive label or brand.

57. Misbranding—Foods—Substances Required to Be Named.

Alcohol, if present in any food product, need not be named on the label.[95] If present in a drug or medicinal preparation, it must be named.[96] With the exception of alcohol all of the substances required to be named if present in drugs or medicinal preparations, are required to be named if present in food products.[97] The Regulations with respect to the statement of these substances and their quantities or properties are the same in case of foods as in case of drugs. (See pages 50 and 51).

It would not seem that morphine, opium, etc., have any legitimate place in food products, and that any product containing any of these substances should be treated as a drug, not a food.

58. Misbranding—Foods—Weights and Measures.

The third paragraph under "food," in Section 8[98] is not to be understood as requiring weight or measure to be stated on a package, but it does require that if stated the weight or

[94]Page 91.
[95]F. I. D. 47, Page 113; F. I. D. 52, Page 116.
[96]Sec. 8, Page 78.
[97]Sec. 8, Page 78.
[98]Page 78.

measure must be stated correctly. Under Regulation 29[99] reasonable variation from the stated weight for individual packages is permitted both as regards variations due to filling and weighing, and as regards charges due to evaporation or absorption of moisture.

59. Misbranding—Foods—Mixtures of Compounds Under Distinctive Names.

The first part of the fourth paragraph of Section 8[100] covers the same ground that is already covered by the introductory paragraph of this Section. The prohibition seems to be here repeated in order to lead up to the exceptions which follow it.

"Mixture" or "Compound," the two words being substantially identical in meaning,[101] is construed to mean the result of putting together two or more food products. A mixture of mineral or inert substances having no food value is not a mixture which is permitted under the Act. In fact such a mixture is expressly prohibited by Section 7.[102] Mixtures or compounds of two or more food products are not required to be marked with the names of the ingredients, or even to be labeled with the word "mixture" or "compound" if the mixture or compound is now or may be hereafter known as an article of food under a distinctive name, "distinctive name" meaning either a trade description commonly employed, or the name applied to a proprietary food, but in such case it is required that the label bear a statement of the place where the article was manufactured or produced.[103]

A mixture or compound not known under a distinctive name must be labeled, branded or tagged with the word "mixture" or "compound." Under the rulings of the Secretary of Agriculture it appears that in such cases the word "mixture" or "compound" must stand alone and without qualification.[104]

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[99]Page 98. [100]Page 78. [101]F. I. D. 42, Page 106.
[102]Page 76. [103]Page 79. [104]F. I. D. 47, Page 113.

60. Misbranding — Foods — Permissible Imitations.

The second proviso under the fourth paragraph under "food" of Section 8,[104] seems to permit the sale of an "imitation" of an article of food, provided it is labeled, branded or tagged with the word "imitation."

Paragraph (f) of Regulation 21[105] defines "imitation" as "a counterfeit or fraudulent simulation of any article or food or drug." Doubtless this definition is correct if applied to the imitation which is intended to be prohibited by the first paragraph under "drugs," or the first paragraph under "food" of this Section, and it does not appear that the Act anywhere countenances or permits the sale of anything which is a counterfeit or fraudulent simulation of any article of food or drug. The "imitation" which is permitted by the second proviso under the fourth paragraph under "food" if labeled, branded or tagged to plainly indicate that it is an imitation, with the word "imitation" plainly stated on the package, must necessarily be an article which is wholesome as food and free from deleterious ingredients, capable of or intended for use in the same way as the substance of which it is an imitation and as a substitute for such substance.

In Decision of the Secretary of Agriculture No. 50,[106] January 18, 1907, it is suggested that what has sometimes been termed "Cereal Coffee" should be designated "Imitation Coffee." If by adopting this suggestion the manufacturer is to be understood by the public as admitting that his product is a counterfeit or fraudulent simulation of coffee as defined in paragraph (f) of Regulation 21,[107] it can hardly be expected that he will label, brand or tag his product as "imitation."

Unless the definition of imitation in paragraph (f) of Regulation 21[108] is materially modified, it is probable that the manufacturers of "Cereal Coffee" and other food products designed to be used in place of recognized articles, will prefer to retain the names now used on their goods rather than mark them imitations.

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[104]Page 79. [105]Page 94. [106]Page 115. [107]Page 94. [108]Page 94.

61. Misbranding—Foods—Compounds—Mixtures.

The second paragraph of the proviso of Section 8[109] is clearly intended to permit the sale of food products which are compounds or mixtures, provided they are labeled, branded or tagged so as to plainly indicate what they are. It would seem to be clear that the permission extends to the admixture with a substance of a second substance which reduces or lowers the strength or quality of the first. For instance, the addition to pure mustard of flour or meal to reduce its strength to the ordinary prepared mustard. This would be adulteration under the first paragraph under "food" in Section 7,[110] if the prepared mustard were offered for sale as pure mustard, but it is not to be treated as adulterated if plainly labeled as a mixture or compound. The permission does not extend to mixtures under the fourth paragraph of Section 7[110] made for the purpose of concealing damage or inferiority or to a mixture containing any added poisonous or deleterious ingredients.

"Mixture" and "compound" appear to mean the same thing and are so construed by the Department of Agriculture.[111] They differ from "blends" in that they are not necessarily limited to the product resulting from the mingling together of like substances, while "blend" is expressly so limited by the language of the Act.

A mixture of rye and wheat flour is a mixture or compound and should be so labeled, branded or tagged.[112] It should not be labeled "rye flour" alone. The use of an ingredient in small quantity simply for the sake of naming it in the list of ingredients does not justify so naming it. The ingredients must be present in substantial quantities.

62. Misbranding—Foods—Blends.

Under the second paragraph of the proviso of Section 8 the term "blend" is to be construed as meaning a mixture of "like substances" not excluding harmless coloring or flavoring ingredients used for the purpose of coloring and

[109]Page 79. [110]Page 77 [111]F. I. D. 42, Page 106; F. I. D. 65, Page 129.
[112]F. I. D. 42, Page 106.

flavoring only. Under paragraphs (c) and (d) of Regulation 21[113] coloring and flavoring cannot be used for increasing the weight or bulk of the mixture and are not to be used in quantities to exceed 1 to 800.

In paragraph (e) of Regulation 21[114] it is stated that a color or flavor cannot be employed to imitate any natural product or any other product of recognized name and quality. This evidently to be read with the definition of "imitation" in paragraph (f) of the same Regulation[115] and with the proviso under "food" in Section 8[116] which expressly provides that imitations, if properly labeled, branded or tagged, shall not be deemed to be misbranded. It would seem to be practically impossible to produce even the "imitation" permissible by the Act without the use of color or flavor, and it does not appear that the Act prohibits the use of color or flavor for the production of "imitations" which are offered for sale for what they are and not under any misrepresentation.

For those engaged in the production, manufacture or sale of liquors, particularly whiskey, the question of what are "like substances" under the Act is of great importance, since upon the meaning given these words as used in the final paragraph of Section 8[117] depends the question of the branding or labeling of the liquors made up in part of straight whiskey and in part of ethyl alcohol or spirits. The ruling of the Secretary of Agriculture[118] on this question based on an opinion of the Attorney-General, approved by the President, is that straight whiskey shall be labeled as such, that a mixture of two or more straight whiskeys shall be labeled "blended whiskey" or "blended whiskeys; that a mixture of straight whiskey and ethyl alcohol, provided there is enough whiskey in it to make it a *real* compound or mixture, shall be labeled "compound whiskey," "compounded whiskey" or "compound of pure grain distillates"; and that ethyl alcohol flavored and colored so as to taste,

[113]Page 94. [114]Page 94. [115]Page 94. [116]Page 79.
[117]Page 79. [118]F. I. D. 45, Page 110; F. I. D. 65, Page 129.

smell and look like whiskey shall be labeled imitation whiskey.

The effect of this ruling is to make the use of the word "blend" on liquor composed in part of ethyl alcohol or neutral spirits, and in part only, of whiskey, misbranding under the Act as construed by the Department of Agriculture.

The term "compound whiskey" is not permitted by the ruling, except as applied to a mixture containinlg a substantial proportion of whiskey. The same ruling applies to all other compounds, whether drugs or food products, that is, no preparation can be named after an ingredient which is not present.[119]

63. Misbranding—Proprietary Foods—Formula.

The further proviso clause of the second proviso under "food" of Section 8[120] recognizes the impropriety of so construing any of the provisions of the Act as to compel the manufacturer of a food product made by a secret process or formula to disclose such process or formula, so long as such food product is in itself wholesome and is not labeled or branded in such a way as to deceive the public.

Such proprietary foods are subject to the general provisions of the Act as regards adulteration and misbranding. If upon examination or analysis of samples or specimens of such foods, they are found to contain substances prohibited under the provisions of the Act, or if they are found to be materially different in character or quality from what they are represented to be, the proprietors may be proceeded against as provided for in Sections 4[121] and 5.[122] It will therefore be necessary for the proprietors of such foods to disclose by a statement on the label so much of the formula as may be necessary to comply with the general requirements of the Act regarding misbranding.

It appears from paragraph (a) of Regulation 8[121] that

[119]F. I. D. 63, Page 126. [120]Page 79. [121]Page 75. [122]Page 75.

this portion of the Act is construed to empower the Secretary of Agriculture to decide to what extent the names and percentage of materials used are to be stated on the label. The basis for this regulation does not clearly appear in the Act, nor is there any basis in the Act for the requirement in paragraph (b)[122] of the same regulation requiring the factories in which proprietary foods are made to be open for inspection at all reasonable times.

The Act will probably be construed by the Courts to require the proprietors or manufacturers to see to it that their foods are free from adulteration and are not misbranded, and that for the purpose of avoiding misbranding the formula, or so much thereof as may be necessary, shall be stated on the label, and that the sole duty of the Secretary of Agriculture in the matter of proprietary foods is, as in the matter of any food or drug product, to determine whether from the analysis or examination of samples or specimens it appears that the provisions of the Act have been violated.

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[121]Page 86. [122]Page 86.

CHAPTER VI.

THE GUARANTY.

64. Effect of the Guaranty.

The guaranty contemplated by Section 9[123] is in effect an agreement by the manufacturer, packer, wholesaler or jobber that he will hold himself responsible for the food or drug products furnished by him to dealers. Without a guaranty retail dealers are liable under the Act, even in case of goods in original unbroken packages, if such goods are adulterated or misbranded, and it is no defense under the Act to show that such goods were received from another person and were not known by the retailer to be misbranded or adulterated, unless the person from whom the goods were received assumed responsibility for the character or quality by a written guaranty duly signed by him.

If a guaranty has been filed with the Secretary of Agriculture, the package containing the goods should bear the statement "Guaranteed under the Food and Drugs Act, June 30, 1906, Serial No.——" This statement should not be qualified by any other words. Such statement appearing on a package if no guaranty has in fact been filed, is misbranding under Section 8, for which the party placing it on the package will no doubt be held responsible.

65. Form of Guaranty.

The guaranty may be a general guaranty filed with the Secretary of Agriculture covering all goods manufactured or sold by the guarantor, or all goods bearing certain specified names or trademarks made and sold by him, or it may cover only a particular shipment of goods, in which case it should identify and be attached to the bill of sale, invoice,

[123] Page 80.

bill of lading, or other schedule, giving the names and guaranties of the articles intended to be covered by it.

The guaranty, if filed with the Secretary of Agriculture, should be signed by the guarantor, and, under the present requirement of the Department, should be acknowledged before a notary. In case of a guaranty given by a firm, corporation or association, the member of the firm or officer signing for the corporation should make clear the fact of his authority to sign for the firm, corporation or association. No fee is charged by the Department of Agriculture for filing guaranties and assigning serial numbers.

No particular form of guaranty is prescribed by the Act or by the Rules and Regulations. It should, however, be drawn to cover precisely what it is intended to cover and no more. Wholesalers and jobbers dealing in a wide variety of goods coming to them in original unbroken packages from a wide variety of sources should avoid so drawing their guaranty as to assume responsibility for goods of the character and quality of which they can not be absolutely sure. Care should be taken in this matter particularly with reference to imported goods.

It is probable that guarantees accepted in good faith by dealers will be held sufficient to bind the guarantors and that technical defects in the guarantees will not relieve the guarantors from responsibility.

A wholesaler or jobber who purchases food or drug products from the producer or from anyone else may safely guarantee the goods so purchased to his customers, provided he has from the producer or other person from whom he purchased the goods, a guaranty covering them. In case of such double guaranty, it would be advisable for the wholesaler or jobber before guaranteeing to his customers that such goods are not adulterated or misbranded, to see to it that the guaranty given him by the person from whom he purchased sufficiently identifies the goods to make it possible to readily trace back any of them found to be in fact adulterated or misbranded.

It will probably be found desirable to limit guarantees to goods bearing distinctive trademarks or other marks which belong to the producer or dealer giving the guarantee. Where a producer or packer puts up goods for a wholesaler, jobber or other distributor and delivers them without labels, to be subsequently labeled, he cannot under his guaranty be responsible for the correctness of such subsequently attached label. If, however, the producer or packer applies labels furnished by the purchaser, his guaranty may properly cover both the question of adulteration and the question of misbranding.

66. Guaranty Applies to Unbroken Packages Only.

A guaranty will be effective to relieve the dealer from responsibility only so long as the package remains unbroken. This is clearly the case as regards sales in the States and would seem to be also true as regards sales in the District of Columbia and the Territories. The guarantor can fairly be held responsible only for goods which reach the consumer in the same condition in which they left his hands. If the package is opened by the retailer, whether re-sold or not, he thereby assumes responsibility for adulteration or misbranding whether actually known to him or not.

67. Guaranty—Not a Government Guaranty.

The guaranty provided for by Section 9[124] is not to be understood as a guaranty by the Department of Agriculture that the goods to which it applies are not adulterated or misbranded, but as merely an assumption of responsibility by the guarantor which does not relieve him from prosecution if the goods are in fact adulterated or misbranded.

Any statement on a label or package indicating that the Government or the Department of Agriculture guarantees the contents of the package is a false or misleading statement and as such is clearly prohibited by Section 8.[125] See Decision of the Secretary of Agriculture No. 40,[126] October 25, 1906.

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[124]Page 80. [125]Page 78. [126]Page 105.

68. Guaranty—No Provision as to Imported Foods or Drugs.

There is no provision for a guaranty by a manufacturer or other person located abroad, such manufacturer or other person being beyond the jurisdiction of the United States Courts. Imported Foods and Drugs may be guaranteed by the importer or any person in the United States. Unless so guaranteed, imported foods and drugs are sold by dealers at their own risk. But in view of the stringency of the laws heretofore in force as well as the provisions of this Act respecting importations, it may generally be assumed that foods and drugs which are permitted to be imported are not adulterated or misbranded.

CHAPTER VII.

MISCELLANEOUS NOTES.

69. Enforcement of the Act.

The course which will be pursued by the Department of Agriculture in the enforcement of the provisions of the Act was expressed by Dr. Wiley, Chief of the Bureau of Chemistry, in his statement at the opening of the hearings before the Commission appointed to formulate the rules and regulations held in New York in September, 1906, in the statement that it was desired in the formulation of the rules and regulations "to secure the purpose in view with the least possible disturbance to business conditions and with the least possible annoyance to the manufacturer, the jobber and the public." This should not, however, be understood as indicating that the Department will permit a reasonable forbearance from an immediate enforcement of the strict letter of the law to be taken advantage of. In commenting on a circular sent out by an association of dealers in food products the Secretary of Agriculture is reported to have said: "The law is now in force and any merchant or manufacturer who violates it does so at his peril. If any of these gentlemen think they can defy the law with impunity let them try it and I will undertake to assure them, eventually, a summons to appear before a United States Court."

70. Stock on Hand.

As regards foods and drugs on hand at the time the law went into force, labels on hand and other matters in which a stringent enforcement of the law would result in serious loss to manufacturers or dealers, the law will undoubtedly be administered with the utmost consideration provided goods on hand are not seriously injurious and are not sold under misrepresentation, and provided that labels on hand

are corrected so far as necessary by supplemental labels, stamps or pasters.

With regard to the use of colors and preservatives on which no definite rulings have yet been given out, it may be expected that after the rulings are given out a reasonable time will be given for the disposal of goods on hand which contain colors or preservatives prohibited by such rulings. The same may be expected with regard to the matter of the marking of the so-called blended whiskeys.

71. Notes as to Particular Products.

All food products, including confectionery, in which artificial coloring or flavoring is used should be so labeled as to clearly indicate that they contain artificial color or flavor. The Department of Agriculture has indicated that in such cases the word "imitation" rather than "artificial" should be used on the label.

Mince meat and pork and beans are considered food products coming under the provisions of this Act, not meat products coming under the Meat Inspection Law.

In the manufacture of sugar, sulphur, phosphoric acid and lime may be used, also tin crystals and zinc dust as bleach, provided the resultant molasses, if shipped out of the State within which it is made, is sold for distilling purposes only. Coloring agents or adulterants such as tin crystals, rock compounds, ultramarine blue, etc., are prohibited.

Gelatine is not prohibited as an ingredient in confectionery or other food product. There is no objection to gelatine made from good, unobjectionable raw material in a sanitary way.

Cocoas in the preparation of which alkalies or other substances have been employed in order to increase the apparent solubility of the product, should bear on the label a declaration of such treatment. The phrase "prepared with alkali" (or alkalies) or "manufactured with alkali" (or alkalies), or some similar statement, would be a sufficient notification.

72. Labeling Packages.

The original unbroken package, that is the case, box, barrel or other package in which cans, bottles, cartons or other retail packages are shipped from the producer, manufacturer or packer to the wholesaler, jobber or retailer, or are shipped from the wholesaler or jobber to his customers, should, if it is shipped from one State to another, be labeled or branded strictly in accordance with the requirements of the Act, and unless some controlling reason exists for doing otherwise, should be labeled or branded strictly in accordance with the rules and regulations and the requirements of the Department of Agriculture. The Act applies directly to the original package.

As regards the labels on the individual cans, bottles, cartons, or other packages enclosed in the case, box, barrel, or other outer package, it is advisable that these conform strictly to the requirements regarding labels contained in the Act, and unless some controlling reason exists for doing otherwise, such labels should conform strictly to the rules and regulations and the requirements of the Department of Agriculture. It is probable, however, that the Act does not apply to the labeling of the retail packages enclosed within an outer package and shipped from one State to another, and it will therefore be sufficient if the retail packages are labeled or branded in conformity with the laws of the State into which they are shipped and in which they are sold. So far as many of the States are concerned, the fact that the Act does not apply to the retail package is not of much practical importance as the laws of many of the States make substantially the same requirements as regards labels which are made by the Act.

With regard to drugs or food products shipped into or out of the District of Columbia or into or out of any Territory the requirements regarding labeling or branding apply to the individual or retail package as well as to the enclosing case, box, barrel, or other package, and it is necessary

that each bottle, can, carton, or other retail package of drugs or food products manufactured in the District of Columbia, or a Territory, or shipped into the District of Columbia, or a Territory, for sale therein, or shipped from the District of Columbia or a Territory, shall be labeled or branded in strict conformity with the requirements of the Act and with the rules and regulations and the requirements of the Department of Agriculture. It is necessary also that the enclosing case, box, barrel or other outer package, in case of drugs or food products manufactured in, or shipped into or out of the District of Columbia or a Territory, shall also be correctly labeled or branded.

73. Canned Goods—Labels.

The labels commonly used on canned goods are in the following form:

[Trademark name.]	[Trademark name.]
[Design.]	[Trademark.]
[Name of particular goods.]	[Packer's name.] [Address.]

While labels in this form are not precisely in the form specified in Regulation 17 (b),[123] or F. I. D. 52,[124] they conform to all the requirements of the Act and may continue to be used without objection on the part of the Department of Agriculture. Of course, if the wholesaler's, jobber's or dealer's name appears on the label, the words "packed for," distributed by," or other words indicating that such name is not the name of the packer, must be used, and it is of course to be understood that the label used, whether in the above form, or in any other form, contains no misrepresentation or false or misleading statement, design or device.

74. State Laws.

In nearly all of the States laws regarding the adultera-

[123]Page 90. [124]Page 116.

tion and misbranding of food and drug products have either been enacted and are now in force, or are under consideration and likely to be adopted in the near future. Such laws in their purpose and in general requirements as to labeling or branding are similar to the Food and Drugs Act, June 30, 1906, a number of them being drawn to conform closely to the Act. Generally speaking, food or drug products which are labeled or branded in conformity with the requirements of the Act, the rules and regulations and the requirements of the Department of Agriculture, will be found to meet the requirements of the laws of any of the States. The definitions of what constitutes adulteration are substantially the same in the State laws as in the Act. In a few of the States, notably Minnesota, Kansas, Indiana, Illinois, and North and South Dakota, the use of analine colors or coal tar preservatives in food products, particularly confectionery, is strictly prohibited. Certain states also make special requirements regarding the labeling of baking powder and a few other articles. A number of States also make stringent requirements regarding proprietary medicines.

APPENDIX.

THE FOOD AND DRUGS ACT, JUNE 30, 1906.

AN ACT for preventing the manufacture, sale, or transportation of adulterated or misbranded or poisonous or deleterious foods, drugs, medicines, and liquors, and for regulating traffic therein, and for other purposes.[1]

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled, That it shall be unlawful for any person to manufacture[2] within any Territory or the District of Columbia any article of food or drug which is adulterated or misbranded, within the meaning of this Act; and any person who shall violate any of the provisions of this section shall be guilty of a misdemeanor, and for each offense shall, upon conviction thereof, be fined not to exceed five hundred dollars or shall be sentenced to one year's imprisonment, or both such fine and imprisonment, in the discretion of the court, and for each subsequent offense and conviction thereof shall be fined not less than one thousand dollars or sentenced to one year's imprisonment, or both such fine and imprisonment, in the discretion of the court.

SEC. 2. That the introduction[3] into any State or Territory or the District of Columbia from any other State or Territory or the District of Columbia, or from any foreign country, or shipment to any foreign country[4] of any article of food or drugs which is adulterated or misbranded, within the meaning of this Act, is hereby prohibited; and any per-

[1]Pages 1, 36, F. I. D., 44, Page 109; F. I. D. 65, Page 129.
[2]Pages 2, 5, 7. [3]Page 3. [4]Page 9, Reg. 31, Page 99.

son who shall ship or deliver for shipment[5] from any State or Territory or the District of Columbia to any other State or Territory or the District of Columbia, or to a foreign country, or who shall receive in any State or Territory or the District of Columbia from any other State or Territory or the District of Columbia, or foreign country, and having so received, shall deliver, in original unbroken packages,[6] for pay or otherwise, or offer to deliver to any other person, any such article so adulterated or misbranded within the meaning of this Act, or any person who shall sell or offer for sale in the District of Columbia or the Territories of the United States any such adulterated or misbranded foods or drugs, or export or offer to export the same to any foreign country, shall be guilty of a misdemeanor, and for such offense be fined not exceeding two hundred dollars for the first offense, and upon conviction for each subsequent offense not exceeding three hundred dollars or be imprisoned not exceeding one year, or both, in the discretion of the court: *Provided*, That no article shall be deemed misbranded or adulterated within the provisions of this Act when intended for export[7] to any foreign country and prepared or packed according to the specifications or directions of the foreign purchaser when no substance is used in the preparation or packing thereof in conflict with the laws of the foreign country to which said article is intended to be shipped; but if said article shall be in fact sold or offered for sale for domestic use or consumption, then this proviso shall not exempt said article from the operation of any of the other provisions of this Act.

SEC. 3. That the Secretary of the Treasury, the Secretary of Agriculture, and the Secretary of Commerce and Labor[8] shall make uniform rules and regulations for carrying out the provisions of this Act, including the collection[9] and examination[10] of specimens of foods and drugs manufactured or offered for sale in the District of Columbia, or in any Ter-

[5]Page 3.
[6]Pages 3, 4, 5, 7, 8, 14, 22, 49, 63, 64, 65.
[7]Page 3, Reg. 31, Page 99.
[8]Page 13.
[9]Pages 13, 14, 15, Reg. 3, Page 84.
[10]Pages 6, 15, 26, 28, 33, 50, Reg. 4, Page 84.

ritory of the United States, or which shall be offered for sale in unbroken packages[11] in any State other than that in which they shall have been respectively manufactured or produced, or which shall be received from any foreign country, or intended for shipment to any foreign country, or which may be submitted for examination by the chief health, food, or drug officer of any State, Territory, or the District of Columbia, or at any domestic or foreign port through which such product is offered for interstate commerce, or for export or import between the United States and any foreign port or country.

SEC. 4. That the examinations of specimens of foods and drugs[12] shall be made in the Bureau of Chemistry of the Department of Agriculture, or under the direction and supervision of such Bureau, for the purpose of determining from such examinations whether such articles are adulterated or misbranded within the meaning of this Act; and if it shall appear from any such examination that any of such specimens is adulterated or misbranded within the meaning of this Act, the Secretary of Agriculture shall cause notice thereof to be given to the party from whom such sample was obtained.[13] Any party so notified shall be given an opportunity to be heard, under such rules and regulations as may be prescribed as aforesaid, and if it appears that any of the provisions of this Act have been violated by such party, then the Secretary of Agriculture shall at once certify the facts to the proper United States district attorney,[14] with a copy of the results of the analysis or the examination of such article duly authenticated by the analyst or officer making such examination, under the oath of such officer. After judgment of the court, notice shall be given by publication in such manner as may be prescribed by the rules and regulations aforesaid.[15]

SEC. 5. That it shall be the duty of each district attorney to whom the Secretary of Agriculture shall report any viola-

[11]Pages 3, 4, 5, 7, 8, 14, 22, 49, 63, 64, 65.
[12]Pages 6, 15, 26, 28, 33, 50.
[13]Page 14, Reg. 3, Page 84.
[14]Page 16, Reg. 5, Page 85.
[15]Page 17, Reg. 6, Page 86.

tion of this Act, or to whom any health or food or drug officer or agent of any State, Territory, or the District of Columbia shall present satisfactory evidence of any such violation, to cause appropriate proceedings[16] to be commenced and prosecuted in the proper courts of the United States, without delay, for the enforcement of the penalties as in such case herein provided.

SEC. 6. That the term "drug,"[17] as used in this Act, shall include all medicines and preparations recognized in the United States Pharmacopœia or National Formulary[18] for internal or external use, and any substance or mixture of substances intended to be used for the cure, mitigation, or prevention of disease of either man or other animals. The term "food,"[19] as used herein, shall include all articles used for food, drink, confectionery, or condiment by man or other animals, whether simple, mixed, or compound.

SEC. 7. That for the purposes of this Act an article shall be deemed to be adulterated:[20]

In case of drugs:

First. If, when a drug is sold under or by a name recognized in the United States Pharmacopœia or National Formulary,[21] it differs from the standard of strength, quality, or purity, as determined by the test laid down in the United States Pharmacopœia or National Formulary official at the time of investigation:[22] *Provided,*[23] That no drug defined in the United States Pharmacopœia or National Formulary shall be deemed to be adulterated under this provision if the standard of strength, quality, or purity be plainly stated upon the bottle, box, or other container thereof although the standard may differ from that determined by the test laid down in the United States Pharmacopœia or National Formulary.

Second. If its strength or purity fall below the professed standard or quality under which it is sold.[24]

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[16]Page 17.
[17]Pages 19, 49.
[18]Pages 22, 23, 46, 47, 48, 49, Reg. 7, Page 86.
[19]Page 20.
[20]Pages 21 to 35.
[21]Pages 22, 23, 46, 47, 48, 49, Reg. 7, Page 86.
[22]Page 23, F. I. D. 59, Page 124.
[23]Page 22, Reg. 7, Page 86.
[24]Page 22, Reg. 7, Page 86.

In the case of confectionery:[25]

If it contain terra alba, barytes, talc, chrome yellow, or other mineral substance or poisonous color or flavor, or other ingredient deleterious or detrimental to health, or any vinous, malt, or spirituous liquor or compound or narcotic drug.[26]

In the case of food:[27]

First. If any substance has been mixed and packed with it so as to reduce or lower or injuriously affect its quality or strength.[28]

Second. If any substance has been substituted wholly or in part for the article.[29]

Third. If any valuable constituent of the article has been wholly or in part abstracted.[30]

Fourth. If it be mixed,[31] colored,[32] powdered,[33] coated,[34] or stained[35] in a manner whereby damage or inferiority is concealed.

Fifth. If it contain any added[36] poisonous or other added deleterious ingredient[37] which may render such article injurious to health:[38] *Provided,* That when in the preparation of food products for shipment they are preserved by any external application applied in such manner that the preservative is necessarily removed mechanically, or by maceration in water, or otherwise,[39] and directions for the removal of said preservative shall be printed on the covering or the package, the provisions of this Act shall be construed as applying only when said products are ready for consumption.

Sixth.[40] If it consists in whole or in part of a filthy, decomposed, or putrid animal or vegetable substance, or any

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[25]Pages 20, 24, 33, Reg. 10, Page 87.
[26]Page 34.
[27]Page 20.
[28]Pages 21, 24, 25, Reg. 11, page 88.
[29]Page 25, Reg. 25, Page 95.
[30]Page 26.
[31]Page 27, Reg. 11, Page 88.
[32]Page 27, Reg. 12, Page 88.
[33]Page 27, Reg. 12, Page 88.
[34]Page 28, Reg. 12, Page 88.
[35]Page 28, Reg. 12, Page 88.
[36]Page 28, Reg. 13, Page 88; Reg. 24, Page 94; F. I. D. 42, Page 106.
[37]Pages 28, 29, 30, 34, Reg. 15, Page 89.
[38]Pages 28, 29, 30, 34, Reg. 15, Page 89.
[39]Page 28; Reg. 14, Page 89.
[40]Pages 32, 33, Reg. 16, Page 90.

portion of an animal unfit for food, whether manufactured or not, or if it is the product of a diseased animal, or one that has died otherwise than by slaughter.[41]

SEC. 8. That the term "misbranded,"[42] as used herein, shall apply to all drugs, or articles of food, or articles which enter into the composition of food, the package or label[43] of which shall bear any statement, design, or device[44] regarding such article, or the ingredients or substances contained therein which shall be false or misleading in any particular,[45] and to any food or drug product which is falsely branded as to the State, Territory, or country in which it is manufactured or produced.[46]

That for the purposes of this Act an article shall also be deemed to be misbranded:

In case of drugs:

First. If it be an imitation of or offered for sale under the name of another article.[47]

Second. If the contents of the package as originally put up shall have been removed, in whole or in part, and other contents shall have been placed in such package,[48] or if the package fail to bear a statement on the label of the quantity or proportion of any alcohol, morphine, opium, cocaine, heroin, alpha or beta eucaine, chloroform, cannabis indica, chloral hydrate, or acetanilide, or any derivative or preparation of any such substances contained therein.[49]

In the case of food:

First. If it be an imitation of or offered for sale under the distinctive name of another article.[50]

Second. If it be labeled or branded so as to deceive or mislead the purchaser, or purport to be a foreign product[51]

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[41]Pages 32, 33, Reg. 16, Page 90.

[42]Pages 36 to 63.

[43]F. I. D. 52, Page 116; Pages 8, 46, 47, 48, 52, 71, Reg. 17, Page 90, F. I. D. 42, Page 106.

[44]Pages 40, 42, Reg. 17, Page 90.

[45]Pages 40, 42, 63, 66, Reg. 17, Page 90.

[46]Pages 37, 39, 43, 45, 54, 55, Reg. 19, Page 93; Reg. 27, Page 95.

[47]Page 48.

[48]Page 49.

[49]Page 49; Reg. 28, Page 96; F. I. D. 54, Page 119; F. I. D. 55, Page 119; F. I. D. 56, Page 120.

[50]Pages 25, 46, 48, 54, 60, 61; Reg. 21, Page 94; F. I. D. 47, Page 113; F. I. D. 50, Page 115; F. I. D. 65, Page 129.

[51]Pages 54, 55, 56; Reg. 17, Page 91; Reg. 19; Page 93.

when not so,[52] or if the contents of the package as originally put up shall have been removed in whole or in part and other contents shall have been placed in such package,[53] or if it fail to bear a statement on the label of the quantity or proportion of any morphine, opium, cocaine, heroin, alpha or beta eucaine, chloroform, cannabis indica, chloral hydrate, or acetanilide, or any derivative or preparation of any of such substances contained therein.[54]

Third. If in package form, and the contents are stated in terms of weight or measure, they are not plainly and correctly stated on the outside of the package.[55]

Fourth. If the package containing it or its label[56] shall bear any statement, design, or device regarding the ingredients or the substances contained therein, which statement, design, or device shall be false or misleading in any particular:[57] *Provided,* That an article of food which does not contain any added poisonous or deleterious ingredients[58] shall not be deemed to be adulterated or misbranded in the following cases:

First: In the case of mixtures or compounds[59] which may be now or from time to time hereafter known as articles of food, under their own distinctive names, and not an imitation of or offered for sale under the distinctive name of another article, if the name be accompanied on the same label or brand with a statement of the place where said article has been manufactured or produced.[60]

Second In the case of articles labeled, branded, or tagged so as to plainly indicate that they are compounds,[61] imitations,[62] or blends,[63] and the word "compound," "imitation," or "blend," as the case may be, is plainly stated on the pack-

[52]Pages 37, 39, 43, 45, 54, 55; Reg. 19, Page 93.
[53]Pages 49, 56.
[54]Page 50, Reg. 28, Page 97.
[55]Pages 37, 57, Reg. 29, Page 98.
[56]See note 43, Page 78.
[57]Pages 40, 42, Reg. 17, Page 90.
[58]Pages 28, 29, 30, 34, Reg. 15, Page 89.
[59]Pages 25, 27, 58, 59, 60, 61, 63; Reg. 21, Page 93; F. I. D. 42, Page 106; F. I. D. 65, Page 129.
[60]Pages 44, 58; Reg. 27, Page 96.
[61]Pages 25, 27, 58, 59, 60, 61, 62; F. I. D. 42, Page 106; F. I. D. 65, Page 129.
[62]Pages 25, 54, 59; Reg. 21, Page 94; F. I. D. 42, Page 106; F. I. D. 65, Page 129.
[63]Pages 25, 27, 61, 62; Reg. 21, Page 93; F. I. D. 42, Page 106; F. I. D. 65, Page 129.

age in which it is offered for sale: *Provided,* That the term blend as used herein shall be construed to mean a mixture of like substances,[64] not excluding harmless coloring or flavoring ingredients used for the purpose of coloring and flavoring only: *And provided further,* That nothing in this Act shall be construed as requiring or compelling proprietors or manufacturers of proprietary foods[65] which contain no unwholesome added ingredient to disclose their trade formulas, except in so far as the provisions of this Act may require to secure freedom from adulteration or misbranding.[67]

SEC. 9.[68] That no dealer shall be prosecuted under the provisions of this Act when he can establish a guaranty signed by the wholesaler, jobber, manufacturer, or other party residing in the United States, from whom he purchases such articles, to the effect that the same is not adulterated or misbranded within the meaning of this Act, designating it. Said guaranty, to afford protection, shall contain the name and address of the party or parties making the sale of such articles to such dealer, and in such case said party or parties shall be amenable to the prosecutions, fines, and other penalties which would attach, in due course, to the dealer under the provisions of this Act.[69]

SEC. 10. That any article of food, drug, or liquor that is adulterated or misbranded within the meaning of this Act, and is being transported from one State, Territory, District, or insular possession to another for sale, or, having been transported, remains unloaded, unsold, or in original unbroken packages, or if it be sold or offered for sale in the District of Columbia or the Territories, or insular possessions of the United States, or if it be imported from a foreign country for sale, or if it is intended for export to a foreign country, shall be liable to be proceeded against in any district court of the United States within the district

[64]Page 62; F. I. D. 65, Page 129.
[65]Pages 25, 62; Reg. 8, Page 86.
[67]Page, 62 Reg. 8, Page 86.
[68]Pages 64 to 76, Reg. 9, Page 87.
[69]Secs. 1 and 2, Pages 73, 74.

where the same is found, and seized[70] for confiscation by a process of libel for condemnation. And if such article is condemned as being adulterated or misbranded, or of a poisonous or deleterious character, within the meaning of this Act, the same shall be disposed of by destruction or sale, as the said court may direct, and the proceeds thereof, if sold, less the legal costs and charges, shall be paid into the Treasury of the United States, but such goods shall not be sold in any jurisdiction contrary to the provisions of this Act or the laws of that jurisdiction: *Provided, however,* That upon the payment of the costs of such libel proceedings and the execution and delivery of a good and sufficient bond to the effect that such articles shall not be sold or otherwise disposed of contrary to the provisions of this Act, or the laws of any State, Territory, District, or insular possession, the court may by order direct that such articles be delivered to the owner thereof. The proceedings of such libel cases shall conform, as near as may be, to the proceedings in admiralty, except that either party may demand trial by jury of any issue of fact joined in any such case, and all such proceedings shall be at the suit of and in the name of the United States.

SEC. 11.[71] The Secretary of the Treasury shall deliver to the Secretary of Agriculture, upon his request from time to time, samples of foods and drugs which are being imported into the United States or offered for import,[72] giving notice thereof to the owner of consignee, who may appear before the Secretary of Agriculture, and have the right to introduce testimony, and if it appear from the examination of such samples that any article of food or drug offered to be imported into the United States is adulterated or misbranded within the meaning of this Act, or is otherwise dangerous to the health of the people of the United States, or is of a kind forbidden entry into, or forbidden to be sold or restricted in sale in the country in which it is made or from

[70]Page 11.
[71]Pages 9, 10, 13.
[72]Pages 9, 10, 13, Regs. 33 to 38, Pages 100 to 102.

which it is exported, or is otherwise falsely labeled in any respect, the said article shall be refused admission, and the Secretary of the Treasury shall refuse delivery to the consignee and shall cause the destruction of any goods refused delivery which shall not be exported by the consignee within three months from the date of notice of such refusal under such regulations as the Secretary of the Treasury may prescribe: *Provided,* That the Secretary of the Treasury may deliver to the consignee such goods pending examination and decision in the matter on execution of a penal bond for the amount of the full invoice value of such goods, together with the duty thereon, and on refusal to return such goods for any cause to the custody of the Secretary of the Treasury, when demanded, for the purpose of excluding them from the country, or for any other purpose, said consignee shall forfeit the full amount of the bond: *And provided further,* That all charges for storage, cartage, and labor on goods which are refused admission or delivery shall be paid by the owner or consignee, and in default of such payment shall constitute a lien against any future importation made by such owner or consignee.

SEC. 12. That the term "Territory" as used in this Act shall include the insular possessions of the United States.[74] The word "person" as used in this Act shall be construed to import both the plural and the singular, as the case demands, and shall include corporations, companies, societies and associations. When construing and enforcing the provisions of this Act, the act, omission, or failure of any officer, agent, or other person acting for or employed by any corporation, company, society, or association, within the scope of his employment or office, shall in every case be also deemed to be the act, omission, or failure of such corporation, company, society, or association as well as that of the person.

SEC. 13. That this Act shall be in force and effect from and after the first day of January, nineteen hundred and seven.

Approved, June 30, 1906.

UNITED STATES DEPARTMENT OF AGRICULTURE.

OFFICE OF THE SECRETARY—*Circular No. 21*

LETTER OF TRANSMITTAL.

WASHINGTON, D. C., *October 16, 1906.*

The Secretaries of the Treasury, of Agriculture, and of Commerce and Labor.

SIRS: The Commission appointed to represent your several Departments in the formulation of uniform rules and regulations for the enforcement of the food and drugs act, approved June 30, 1906, has reached a unanimous agreement and respectfully submits the results of its deliberations and recommends their adoption.

Very respectfully,

H. W. WILEY,
JAMES L. GERRY,
S. N. D. NORTH.

RULES AND REGULATIONS FOR THE ENFORCEMENT OF THE FOOD AND DRUGS ACT.

GENERAL.

REGULATION 1. SHORT TITLE OF THE ACT.

The act, "For preventing the manufacture, sale, or transportation of adulterated or misbranded or poisonous or deleterious foods, drugs, medicines, and liquors, and for regulating traffic therein, and for other purposes," approved June 30, 1906, shall be known and referred to as "The Food and Drugs Act, June 30, 1906."

REGULATION 2. ORIGINAL UNBROKEN PACKAGE.

(Section 2.)[1]

The term "original unbroken package"[2] as used in this act is the original package, carton, case, can, box, barrel, bottle, phial, or other receptacle put up by the manufacturer, to which the label is attached, or which may be suitable for

[1] Page 73.

[2] Pages 3, 4, 5, 7, 8, 14, 22, 49, 64, 65, 66.

the attachment of a label, making one complete package of the food or drug article. The original package contemplated includes both the wholesale and the retail package.

Regulation 3. Collection of Samples.[3]

(Section 4.)[4]

Samples of unbroken packages shall be collected only by authorized agents of the Department of Agriculture; or by the health, food, or drug officer of any State, Territory, or the District of Columbia, when commissioned by the Secretary of Agriculture for this purpose.

Samples may be purchased[5] in the open market, and if in bulk the marks, brands, or tags upon the package, carton, container, wrapper, or accompanying printed or written matter shall be noted. The collector shall also note the names of the vendor and agent thru whom the sale was actually made, together with the date of purchase. The collector shall purchase representative samples.

A sample shall be divided into three parts,[6] and each part shall be labeled with the identifying marks. All samples shall be sealed by the collector with a seal provided for the purpose. If the package be less than 4 pounds, or in volume less than 2 quarts, three packages of approximately the same size shall be purchased and the marks and tags upon each noted as above. One sample shall be delivered to the party from whom purchased or to the party guaranteeing such merchandise.[7] One sample shall be sent to the Bureau of Chemistry, or to such chemist or examiner as may be designated by the Secretary of Agriculture, and the third sample shall be held under seal by the Secretary of Agriculture.

Regulation 4. Methods of Analysis.[8]

(Section 4.)[9]

Unless otherwise directed by the Secretary of Agriculture, the methods of analysis employed shall be those pre-

[3]Pages 13, 14.
[4]Page 75.
[5]Page 13.
[6]Page 13.
[7]Pages 13, 64.
[8]Pages 6, 15.
[9]Page 75.

scribed by the Association of Official Agricultural Chemists and the United States Pharmacopœia.

REGULATION 5. HEARINGS.

(Section 4.)[10]

(*a*) When the examination or analysis shows that the provisions of the food and drugs act, June 30, 1906, have been violated, notice of that fact, together with a copy of the findings, shall be furnished to the party or parties from whom the sample was obtained or who executed the guaranty as provided in the food and drugs act, June 30, 1906, and a date shall be fixt at which such party or parties may be heard before the Secretary of Agriculture, or such other official connected with the food and drug inspection service as may be commissioned by him for that purpose. The hearings shall be had at a place, to be designated by the Secretary of Agriculture, most convenient for all parties concerned. These hearings shall be private and confined to questions of fact. The parties interested therein may appear in person or by attorney and may propound proper interrogatories and submit oral or written evidence to show any fault or error in the findings of the analyst or examiner. The Secretary of Agriculture may order a re-examination of the sample or have new samples drawn for further examination.

(*b*) If the examination or analysis be found correct the Secretary of Agriculture shall give notice to the United States district attorney as prescribed.[11]

(*c*) Any health, food, or drug officer or agent of any State, Territory, or the District of Columbia who shall obtain satisfactory evidence of any violation of the food and drugs act, June 30, 1906, as provided in section 5 thereof, shall first submit the same to the Secretary of Agriculture, in order that the latter may cause notice to be given to the guarantor or to the party from whom the sample was obtained.

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[10]Page 75. [11]Page 16.

REGULATION 6. PUBLICATION.

(Section 4.)[12]

(*a*) When a judgment of the court shall have been rendered there may be a publication of the findings of the examiner or analyst, together with the findings of the court.[13]

(*b*) This publication may be made in the form of circulars, notices, or bulletins, as the Secretary of Agriculture may direct, not less than thirty days after judgment.

(*c*) If an appeal be taken from the judgment of the court before such publication, notice of the appeal shall accompany the publication.[14]

REGULATION 7. STANDARDS FOR DRUGS.

(Section 7.)[15]

(*a*) A drug bearing a name recognized in the United States Pharmacopœia or National Formulary, without any further statement respecting its character, shall be required to conform in strength, quality, and purity to the standards prescribed or indicated for a drug of the same name recognized in the United States Pharmacopœia or National Formulary, official at the time.

(*b*) A drug bearing a name recognized in the United States Pharmacopœia or National Formulary, and branded to show a different standard of strength, quality, or purity, shall not be regarded as adulterated if it conforms to its declared standard.

REGULATION 8. FORMULAS—PROPRIETARY FOODS.

(Section 8,[16] last paragraph.)

(*a*) Manufacturers of proprietary foods are only required to state upon the label the names and percentages of the materials used, in so far as the Secretary of Agriculture may find this to be necessary to secure freedom from adulteration and misbranding.[17]

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[12]Page 75.
[13]Page 17.
[14]Page 18.
[15]Page 76.
[16]Page 79.

(*b*) The factories in which proprietary foods are made shall be open at all reasonable times to the inspection provided for in Regulation 16.[18]

Regulation 9. Form of Guaranty.

(Section 9.)[19]

(*a*) No dealer in food or drug products will be liable to prosecution if he can establish that the goods were sold under a guaranty by the wholesaler, manufacturer, jobber, dealer, or other party residing in the United States from whom purchased.[20]

(*b*) A general guaranty may be filed with the Secretary of Agriculture by the manufacturer or dealer and be given a serial number, which number shall appear on each and every package of goods sold under such guaranty with the words, "Guaranteed under the food and drugs act, June 30, 1906."[21]

(*c*) The following form of guaranty is suggested.[22]

I (we) the undersigned do hereby guarantee that the articles of foods or drugs manufactured, packed, distributed, or sold by me (us) [specifying the same as fully as possible] are not adulterated or misbranded within the meaning of the food and drugs act, June 30, 1906.

(Signed in ink.) ——— ———.

[Name and place of business of wholesaler, dealer, manufacturer, jobber, or other party.]

(*d*) If the guaranty be not filed with the Secretary of Agriculture as above, it should identify and be attached to the bill of sale, invoice, bill of lading, or other schedule giving the names and quantities of the articles sold.

Adulteration.

Regulation 10. Confectionery.

(Section 7.)[23]

(*a*) Mineral substances of all kinds (except as provided in Regulation 15) are specifically forbidden in confectionery whether they be poisonous or not.

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[17]Pages 5, 7.
[18]Page 89.
[19]Page 80.
[20]Pages 64, 67.
[21]Page 64.
[22]Page 64, F. I. D. 40, Page 105.
[23]Page 77.

(*b*) Only harmless colors or flavors shall be added to confectionery.

(*c*) The term "narcotic drugs" includes all the drugs mentioned in section 8, food and drugs act, June 30, 1906, relating to foods, their derivatives and preparations, and all other drugs of a narcotic nature.

REGULATION 11. SUBSTANCES MIXT AND PACKED WITH FOODS.

(Section 7,[24] under "Foods.")

No substance may be mixt or packed with a food product which will reduce or lower its quality or strength.[25] Not excluded under this provision are substances properly used in the preparation of food products for clarification or refining, and eliminated in the further process of manufacture.[26]

REGULATION 12. COLORING, POWDERING, COATING, AND STAINING.

(Section 7,[24] under "Foods.")

(*a*) Only harmless colors may be used in food products.[27]

(*b*) The reduction of a substance to a powder to conceal inferiority in character is prohibited.[28]

(*c*) The term "powdered" means the application of any powdered substance to the exterior portion of articles of food, or the reduction of a substance to a powder.

(*d*) The term "coated"[29] means the application of any substance to the exterior portion of a food product.

(*e*) The term "stain"[30] includes any change produced by the addition of any substance to the exterior portion of foods which in any way alters their natural tint.

REGULATION 13. NATURAL POISONOUS OR DELETERIOUS INGREDIENTS.[31]

(Section 7,[24] paragraph 5, under "Foods.")

Any food product which contains naturally a poisonous or deleterious ingredient does not come within the provisions of the food and drugs act, June 30, 1906, except when

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[24]Page 77.
[25]Pages 21, 24, 25.
[26]Pages 25, 50.
[27]Pages 27, 34.
[28]Page 27.
[29]Page 28.
[30]Page 28.
[31]Page 29.

the presence of such ingredient is due to filth, putrescence, or decomposition.

Regulation 14. External Application of Preservatives.[32]

(Section 7,[33] paragraph 5, under "Foods," proviso.)

(*a*) Poisonous or deleterious preservatives shall only be applied externally, and they and the food products shall be of a character which shall not permit the permeation of any of the preservative to the interior, or any portion of the interior, of the product.

(*b*) When these products are ready for consumption, if any portion of the added preservative shall have penetrated the food product, then the proviso of section 7, paragraph 5, under "Foods," shall not obtain, and such food products shall then be subject to the regulations for food products in general.

(*c*) The preservative applied must be of such a character that, until removed, the food products are inedible.

Regulation 15. Wholesomeness of Colors and Preservatives.[34]

(Section 7,[33] paragraph 5, under "Foods.")

(*a*) Respecting the wholesomeness of colors, preservatives, and other substances which are added to foods, the Secretary of Agriculture shall determine from chemical or other examination, under the authority of the agricultural appropriation act, Public 382, approved June 30, 1906, the names of those substances which are permitted or inhibited in food products; and such findings, when approved by the Secretary of the Treasury and the Secretary of Commerce and Labor, shall become a part of these regulations.

(*b*) The Secretary of Agriculture shall determine from time to time, in accordance with the authority conferred by the agricultural appropriation act, Public 382, approved June 30, 1906, the principles which shall guide the use of colors, preservatives, and other substances added to foods;

[32] Pages 28, 31. [33] Page 77.
[34] Page 29, F. I. D. 48, Page 114; F. I. D. 51, Page 115.

and when concurred in by the Secretary of the Treasury and the Secretary of Commerce and Labor, the principles so established shall become a part of these regulations.

REGULATION 16. CHARACTER OF THE RAW MATERIALS.

(Section 7,[34] paragraph 1, under "Drugs;" paragraph 6, under "Foods.")

(*a*) The Secretary of Agriculture, when he deems it necessary, shall examine[35] the raw materials used in the manufacture of food and drug products, and determine whether any filthy, decomposed, or putrid substance is used in their preparation.

(*b*) The Secretary of Agriculture shall make such inspections as often as he may deem necessary.

MISBRANDING.

REGULATION 17. LABEL.[36]

(Section 8.)[37]

(*a*) The term "label" applies to any printed, pictorial, or other matter upon or attached to any package of a food or drug product, or any container thereof.

(*b*) The principal label shall consist, first, of all words which the food and drugs act, June 30, 1906, specifically requires, to wit, the name of the substance or product;[38] the name of place of manufacture[39] in the case of food compounds or mixtures; words which show that the articles are compounds, mixtures, or blends; the words "compound," "mixture," or "blend;" or words designating the substances or their derivatives and proportions required to be named in the case of drugs and foods. All these required words shall appear upon the principal label with no intervening descriptive or explanatory reading matter. Second, if the name of the manufacturer[40] and place of manufacture[41] are given, they shall also appear upon the principal label. Third,

[34]Pages 76, 77.
[35]Pages 5, 7.
[36]Pages 8, 46, 47, 53, 56, 71, F. I. D. 52, Page 116.
[37]Page 78.

elsewhere upon the principal label other matter may appear in the discretion of the manufacturer.[42]

(*c*) The principal label on foods or drugs for domestic commerce shall be printed in English (except as provided in Regulation 19), with or without the foreign label in the language of the country where the food or drug product is produced or manufactured.[43] The size of type shall not be smaller than 8-point (brevier) caps: *Provided,* That in case the size of the package will not permit the use of 8-point cap type the size of the type may be reduced proportionately.

(*d*) The form, character, and appearance of the labels, except as provided above, are left to the judgment of the manufacturer.

(*e*) Descriptive matter upon the label shall be free from any statement, design, or device regarding the article or the ingredients or substances contained therein, or quality thereof, or place of origin, which is false or misleading in any particular.

(*f*) An article containing more than one food product or active medicinal agent is misbranded if named after a single constituent.

In the case of drugs the nomenclature employed by the United States Pharmacopœia and the National Formulary shall obtain.

(*g*) The term "design" or "device" applies to pictorial matter of every description, and to abbreviations, characters, or signs for weights, measures, or names of substances.

(*h*) The use of any false or misleading statement, design, or device shall not be justified by any statement given as the opinion of an expert or other person, appearing on any part of the label, nor by any descriptive matter explaining the use of the false or misleading statement, design, or device.

(*i*) The regulation regarding the principal label will not be enforced until October 1, 1907, in the case of labels

[43] Page 56.

printed and now on hand, whenever any statement therein contained which is contrary to the food and drugs act, June 30, 1906, as to character of contents, shall be corrected by a supplemental label, stamp, or paster. All other labels now printed and on hand may be used without change until October 1, 1907.[44]

REGULATION 18. NAME AND ADDRESS OF MANUFACTURER.
(Section 8.)[45]

(*a*) The name of the manufacturer or producer, or the place where manufactured, except in case of mixtures and compounds having a distinctive name, need not be given upon the label, but if given, must be the true name and the true place.[46] The words "packed for ———," "distributed by ———," or some equivalent phrase, shall be added to the label in case the name which appears upon the label is not that of the actual manufacturer or producer, or the name of the place not the actual place of manufacture or production.[47]

(*b*) When a person, firm, or corporation actually manufactures or produces an article of food or drug in two or more places, the actual place of manufacture or production of each particular package need not be stated on the label except when in the opinion of the Secretary of Agriculture the mention of any such place, to the exclusion of the others, misleads the public.[48]

REGULATION 19. CHARACTER OF NAME.
(Section 8.)[49]

(*a*) A simple or unmixt food or drug product not bearing a distinctive name shall be designated by its common name in the English language, or, if a drug, by any name recognized in the United States Pharmacopœia or National Formulary. No further description of its components or qualities is required, except as to content of alcohol, morphine, etc.

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[44] Pages 8, 53; F. I. D. 43, Page 107.
[45] Page 78.
[46] Pages 41, 42, 47.
[47] Pages 41, 43, 44, 47.
[48] Page 46.
[49] Page 78.

(*b*) The use of a geographical name[50] shall not be permitted in connection with a food or drug product not manufactured or produced in that place, when such name indicates that the article was manufactured or produced in that place.

(*c*) The use of a geographical name[51] in connection with a food or drug product will not be deemed a misbranding when by reason of long usage it has come to represent a generic term and is used to indicate a style, type, or brand; but in all such cases the State or Territory where any such article is manufactured or produced shall be stated upon the principal label.

(*d*) A foreign name[52] which is recognized as distinctive of a product of a foreign country shall not be used upon an article of domestic origin except as an indication of the type or style of quality or manufacture, and then only when so qualified that it can not be offered for sale under the name of a foreign article.

Regulation 20. Distinctive Name.

(Section 8.)[53]

(*a*) A "distinctive name"[54] is a trade, arbitrary, or fancy name which clearly distinguishes a food product, mixture, or compound from any other food product, mixture, or compound.

(*b*) A distinctive name shall not be one representing any single constituent of a mixture or compound.

(*c*) A distinctive name shall not misrepresent any property or quality of a mixture or compound.

(*d*) A distinctive name shall give no false indication of origin, character, or place of manufacture, nor lead the purchaser to suppose that it is any other food or drug product.

Regulation 21. Compounds, Imitations, or Blends Without Distinctive Name.

(Section 8.)[53]

(*a*) The term "blend"[55] applies to a mixture of like substances,[56] not excluding harmless coloring or flavoring in-

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[50] Page 45.
[51] Page 45.
[52] Page 56.
[53] Page 78.
[54] Pages 25, 54, 60.
[55] Pages 25, 27, 61, 62; F. I. D. 42, Page 106; F. I. D. 65, Page 129.
[56] Page 62, F. I. D. 42, Page 106; F. I. D. 45, Page 110; F. I. D. 65, Page 129.

gredients used for the purpose of coloring and flavoring only.

(*b*) If any age is stated, it shall not be that of a single one of its constituents, but shall be the average of all constituents in their respective proportions.

(*c*) Coloring and flavoring cannot be used for increasing the weight or bulk of a blend.[57]

(*d*) In order that colors or flavors may not increase the volume or weight of a blend, they are not to be used in quantities exceeding 1 pound to 800 pounds of the blend.

(*e*) A color or flavor can not be employed to imitate any natural product or any other product of recognized name and quality.[58]

(*f*) The term "imitation" applies to any mixture or compound which is a counterfeit or fraudulent simulation of any article of food or drug.[59]

Regulation 22. Articles Without a Label.

(Section 8,[60] paragraph 1, under "Drugs;" paragraph 1, under "Foods.")

It is prohibited to sell or offer for sale a food or drug product bearing no label upon the package or no descriptive matter whatever connected with it, either by design, device, or otherwise, if said product be an imitation of or offered for sale under the name of another article.[61]

Regulation 23. Proper Branding not a Complete Guaranty.

Packages which are correctly branded as to character of contents, place of manufacture, name of manufacturer, or otherwise, may be adulterated and hence not entitled to enter into interstate commerce.[62]

Regulation 24. Incompleteness of Branding.

A compound shall be deemed misbranded if the label be incomplete as to the names of the required ingredients. A simple product does not require any further statement than

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[57] Pages 25, 27, 61, 62, F. I. D. 42, Page 106; F. I. D. 45, Page 110; F. I. D. 65, Page 129.
[58] Page 61.
[59] Page 59, F. I. D. 50, Page 115.
[60] Page 78.
[61] Page 46.
[62] Page 21.

the name or distinctive name thereof, except as provided in Regulations 19 (a)[63] and 28.[64]

REGULATION 25. SUBSTITUTION.

(Sections 7[65] and 8.[66])

(*a*) When a substance of a recognized quality commonly used in the preparation of a food or drug product is replaced by another substance not injurious or deleterious to health, the name of the substituted substance shall appear upon the label.

(*b*) When any substance which does not reduce, lower, or injuriously affect its quality or strength, is added to a food or drug product, other than that necessary to its manufacture or refining, the label shall bear a statement to that effect.

REGULATION 26. WASTE MATERIALS.[67]

(Section 8.)[68]

When an article is made up of refuse materials, fragments, or trimmings, the use of the name of the substance from which they are derived, unless accompanied by a statement to that effect, shall be deemed a misbranding. Packages of such materials may be labeled "pieces," "stems," "trimmings," or with some similar appellation.

REGULATION 27. MIXTURES OR COMPOUNDS WITH DISTINCTIVE NAMES.[69]

(Section 8.[68] First proviso under "Foods," paragraph 1.)

(*a*) The terms "mixtures" and "compounds" are interchangeable and indicate the results of putting together two or more food products.

(*b*) These mixtures or compounds shall not be imitations of other articles, whether simple, mixt, or compound, or offered for sale under the name of other articles. They shall bear a distinctive name and the name of the place where

[63] Page 92.
[64] Page 96.
[65] Page 76.
[66] Page 78.
[67] Pages 26, 55.
[68] Page 78.
[69] Pages 58, 59, F. I. D. 42, Page 106.

the mixture or compound has been manufactured or produced.

(*c*) If the name of the place be one which is found in different States, Territories, or countries, the name of the State, Territory, or country, as well as the name of the place, must be stated.

REGULATION 28. SUBSTANCES NAMED IN DRUGS OR FOODS.

(Section 8.[70] Second under "Drugs;" second under "Foods.")

(*a*) The term "alcohol" is defined to mean common or ethyl alcohol.[71] No other kind of alcohol is permissible in the manufacture of drugs except as specified in the United States Pharmacopœia or National Formulary.

(*b*) The words alcohol, morphine, opium, etc., and the quantities and proportions thereof, shall be printed in letters corresponding in size with those prescribed in Regulation 17, paragraph (c).[72]

(*c*) A drug, or food product except in respect of alcohol, is misbranded in case it fails to bear a statement on the label of the quantity or proportion[73] of any alcohol, morphine, opium, heroin, cocaine, alpha or beta eucaine, chloroform, cannabis indica, chloral hydrate, or acetanilide, or any derivative or preparation of any such substances contained therein.

(*d*) A statement of the maximum quantity or proportion of any such substances present will meet the requirements, provided the maximum stated does not vary materially from the average quantity or proportion.[74]

(*e*) In case the actual quantity or proportion is stated it shall be the average quantity or proportion with the variations noted in Regulation 29.[75]

(*f*) The following are the principal derivatives and preparations made from the articles which are required to be named upon the label.[76]

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[70]Page 78.
[71]Page 51, F. I. D. 43, Page 107.
[72]Page 91.
[73]Page 51, F. I. D. 53, Page 118; F. I. D. 55, Page 119; F. I. D. 56, Page 120.
[74]Page 52.
[75]Page 98.
[76]Page 50, F. I. D. 54, Page 119; F. I. D. 55, Page 119; F. I. D. 57, Page 122.

ALCOHOL, ETHYL : (*Cologne spirits, Grain alcohol, Rectified spirits, Spirits, and Spirits of wine.*)
Derivatives—
Aldehyde, Ether, Ethyl acetate, Ethyl nitrite, and Paraldehyde.
Preparations containing alcohol—
Bitters, Brandies, Cordials, Elixirs, Essences, Fluidextracts, Spirits, Sirups, Tinctures, Tonics, Whiskies, and Wines.

MORPHINE, ALKALOID:
Derivatives—
Apomorphine, Dionine, Peronine, Morphine acetate, Hydrochloride, Sulphate, and other salts of morphine.
Preparations containing morphine or derivatives of morphine—
Bougies, Catarrh Snuff, Chlorodyne, Sompound powder of morphine, Crayons, Elixirs, Granules, Pills, Solutions, Sirups, Suppositories. Tablets, Triturates, and Troches.

OPIUM, GUM:
Preparations of Opium—
Extracts, Denarcotized opium, Granulated opium, and Powdered opium, Bougies, Brown mixture, Carminative mixtures, Crayons, Dover's powder, Elixirs, Liniments, Ointments, Paregoric, Pills, Plasters, Sirups, Suppositories, Tablets, Tinctures, Troches, Vinegars, and Wines.
Derivatives—
Codeine, Alkaloid, Hydrochloride, Phosphate, Sulphate, and other salts of codeine.
Preparations containing codeine or its salts—
Elixirs, Pills, Sirups, and Tablets.

COCAINE, ALKALOID:
Derivatives—
Cocaine hydrochloride, Oleate, and other salts.
Preparations containing cocaine or salts of cocaine—
Coca leaves, Catarrh powders, Elixirs, Extracts, Infusion of coca, Ointments, Paste pencils, Pills, Solutions, Sirups, Tablets, Tinctures, Troches, and Wines.

HEROIN:
Preparations containing heroin—
Sirups, Elixirs, Pills, and Tablets.

ALPHA AND BETA EUCAINE:
Preparations—
Mixtures, Ointments, Powders, and Solutions.

CHLOROFORM:
Preparations containing chloroform—
Chloranodyne, Elixirs, Emulsions, Liniments, Mixtures, Spirits, and Sirups.

CANNABIS INDICA:
Preparations of cannabis indica—
Corn remedies, Extracts, Mixtures, Pills, Powders, Tablets, and Tinctures.

CHLORAL HYDRATE (*Chloral,* U. S. Pharmacopœia, 1890):
Derivatives—
Chloral acetophenonoxim, Chloral alcoholate, Chloralamide,

Chloralimide, Chloral orthoform, Chloralose, Dormiol, Hypnal, and Uraline.

Preparations containing chloral hydrate or its derivatives—
Chloral camphorate, Elixirs, Liniments, Mixtures, Ointments, Suppositories, Sirups, and Tablets.

ACETANILIDE (*Antifebrine, Phenylacetamide*):

Derivatives—
Acetphenetidine, Citrophen, Diacetanilide, Lactophenin, Methoxyacetanilide, Methylacetanilide, Para-Iodoacetanilide, and Phenacetine.

Preparations containing acetanilide or derivatives—
Analgesics, Antineuralgics, Antirheumatics, Cachets, Capsules, Cold remedies, Elixirs, Granular effervescing salts, Headache powders, Mixtures, Pain remedies, Pills, and Tablets.

REGULATION 29. STATEMENT OF WEIGHT OR MEASURE.[76]

(Section 8.[77] Third under "Foods.")

(*a*) A statement of the weight or measure of the food contained in a package is not required.[78] If any such statement is printed, it shall be a plain and correct statement of the average net weight or volume, either on or immediately above or below the principal label, and of the size of letters specified in Regulation 17.[79]

(*b*) A reasonable variation[80] from the stated weight for individual packages is permissible, provided this variation is as often above as below the weight or volume stated. This variation shall be determined by the inspector from the changes in the humidity of the atmosphere, from the exposure of the package to evaporation or to absorption of water, and the reasonable variations which attend the filling and weighing or measuring of a package.

REGULATION 30. METHOD OF STATING QUANTITY OR PROPORTION.

(Section 8.)[77]

In the case of alcohol the expression "quantity" or "proportion"[81] shall mean the average percentage by volume in the finished product. In the case of the other ingredients required to be named upon the label, the expression "quantity" or "proportion"[81] shall mean grains or minims per ounce or

[76]Pages 37, 57, F. I. D. 43, Page 107.
[77]Pages 78, 79.
[78]Page 57.
[79]Page 91.
[80]Page 58.
[81]Pages 51, 52.

fluid ounce, and also, if desired, the metric equivalents therefor, or milligrams per gram or per cubic centimeter, or grams or cubic centimeters per kilogram or per liter; provided that these articles shall not be deemed misbranded if the maximum of quantity or proportion be stated, as required in Regulation 28 (*d*).[82]

Exports and Imports of Foods and Drugs.

Regulation 31. Preparation of Food Products for Export.

(Section 2.)[83]

(*a*) Food products intended for export may contain added substances not permitted in foods intended for interstate commerce, when the addition of such substances does not conflict with the laws of the countries to which the food products are to be exported and when such substances are added in accordance with the directions of the foreign purchaser or his agent.

(*b*) The exporter is not required to furnish evidence that goods have been prepared or packed in compliance with the laws of the foreign country to which said goods are intended to be shipped, but such shipment is made at his own risk.

(*c*) Food products for export under this regulation shall be kept separate and labeled to indicate that they are for export.

(*d*) If the products are not exported they shall not be allowed to enter interstate commerce.

Regulation 32. Imported Food and Drug Products.

(Section 11.)[84]

(*a*) Meat and meat food products[85] imported into the United States shall be accompanied by a certificate of official inspection of a character to satisfy the Secretary of Agriculture that they are not dangerous to health, and each package of such articles shall bear a label which shall iden-

[82]Page 96.
[83]Page 73.
[84]Page 81.
[85]Pages 9, 10, 20.

tify it as covered by the certificate, which certificate shall accompany or be attached to the invoice on which entry is made.

(*b*) The certificate shall set forth the official position of the inspector and the character of the inspection.

(*c*) Meat and meat food products as well as all other food and drug products of a kind forbidden entry into or forbidden to be sold, or restricted in sale in the country in which made or from which exported, will be refused admission.

(*d*) Meat and meat food products which have been inspected and past thu the customs may, if identity is retained, be transported in interstate commerce.

REGULATION 33. DECLARATION.[86]

(Section 11.)[87]

(*a*) All invoices of food or drug products shipped to the United States shall have attached to them a declaration of the shipper, made before a United States consular officer, as follows:

I, the undersigned, do solemnly and truly declare that I am the ——— (Manufacturer, agent, or shipper.) ——— of the merchandise herein mentioned and described, and that it consists of food or drug products which contain no added substances injurious to health.

These products were grown in ——— (Country.) and manufactured in ——— (Country.) by ——— ——— (Name of manufacturer.) during the year ———, and are exported from ——— (City.) and consigned to ——— (City.). The products bear no false labels or marks, contain ——— (Name of added color or preservative.) added coloring matter or preservative ———, and are not of a character to cause prohibition or restriction in the country where made or from which exported.

Dated at —— this —— day of ——, 19 —.

(Signed): —— —— ——.

(*b*) In the case of importations to be entered at New York, Boston, Philadelphia, Chicago, San Francisco, and New Orleans, and other ports where food and drug inspec-

[86]Page 11. [87]Page 81.

tion laboratories shall be established, this declaration shall be attached to the invoice on which entry is made. In other cases the declaration shall be attached to the copy of the invoice sent to the Bureau of Chemistry.

Regulation 34. Denaturing.

(Section 11.)[88]

Unless otherwise declared on the invoice or entry, all substances ordinarily used as food products will be treated as such. Shipments of substances ordinarily used as food products intended for technical purposes must be accompanied by a declaration stating that fact, and must be so denatured as to prevent their use as foods.

Regulation 35. Bond, Imported Foods, and Drugs.

(Section 11.)[88]

Unexamined packages of food and drug products may be delivered to the consignee prior to the completion of the examination to determine whether the same are adulterated or misbranded upon the execution of a penal bond by the consignee in the sum of the invoice value of such goods with the duty added, for the return of the goods to customs custody.

Regulation 36. Notification of Violation of the Law.

(Section 11.)[88]

If the sample on analysis or examination be found not to comply with the law, the importer shall be notified of the nature of the violation, the time and place at which final action will be taken upon the question of the exclusion of the shipment, and that he may be present, and submit evidence, which evidence (Form 15), with a sample of the article, shall be forwarded to the Bureau of Chemistry at Washington, accompanied by report card (Forms 16, 17, 18, 19, and 20).

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[88] Page 81.

REGULATION 37. APPEAL TO THE SECRETARY OF AGRICULTURE AND REMUNERATION.

(Section 11.)[88]

All applications for relief from decisions arising under the execution of the law should be addrest to the Secretary of Agriculture, and all vouchers or accounts for remuneration for samples shall be filed with the chief of the inspection laboratory, who shall forward the same, with his recommendation, to the Department of Agriculture for action.

REGULATION 38. SHIPMENT BEYOND THE JURISDICTION OF THE UNITED STATES.

(Section 11.)[89]

The time allowed the importer for representations regarding the shipment may be extended at his request to permit him to secure such evidence as he desires, provided that this extension of time does not entail any expense to the Department of Agriculture. If at the expiration of this time, in view of the data secured in inspecting the sample and such evidence as may have been submitted by the manufacturers or importers, it appears that the shipment can not be legally imported into the United States, the Secretary of Agriculture shall request the Secretary of the Treasury to refuse to deliver the shipment in question to the consignee, and to require its reshipment beyond the jurisdiction of the United States.

REGULATION 39. APPLICATION OF REGULATIONS.

These regulations shall not apply to domestic meat and meat food products which are prepared, transported, or sold in interstate or foreign commerce under the meat-inspection law and the regulations of the Secretary of Agriculture made thereunder.[90]

REGULATION 40. ALTERATION AND AMENDMENT OF REGULATIONS.

These regulations may be altered or amended at any time,

[88]Page 81. [90]Pages 9, 10, 20.

without previous notice, with the concurrence of the Secretary of the Treasury, the Secretary of Agriculture, and the Secretary of Commerce and Labor.

The above rules and regulations are hereby adopted.

LESLIE M. SHAW,
Secretary of the Treasury.
JAMES WILSON,
Secretary of Agriculture.
VICTOR H. METCALF,
Secretary of Commerce and Labor.

WASHINGTON, D. C., *October* 17, 1906.

UNITED STATES DEPARTMENT OF AGRICULTURE,

BUREAU OF CHEMISTRY.

H. W. WILEY, Chief of Bureau.

FOOD INSPECTION DECISIONS.

(*F. I. D. 40.*)[91]

FILING GUARANTY.

In order that both the Department and the manufacturer may be protected against fraud it is requested that all guaranties of a general character filed with the Secretary of Agriculture in harmony with Regulation 9,[92] Rules and Regulations for the Enforcement of the Food and Drugs Act, June 30, 1906, be acknowledged before a notary or other official authorized to affix a seal. Attention is called to the fact that when a general guaranty has been thus filed every package of articles of food and drugs put up under the guaranty should bear the legend, "Guaranteed under the Food and Drugs Act, June 30, 1906," and also the serial number assigned thereto, if the dealer is to receive the protection contemplated by the guaranty. No other word should go upon this legend or accompany it in any way. Particular attention is called to the fact that nothing should be placed upon the label, or in any printed matter accompanying it, indicating that the guaranty is made by the Department of Agriculture. The appearance of the serial number with the phrase above mentioned upon a label does not exempt it from inspection nor its guarantor from prosecution in case the article in question be found in any way to violate the food and drugs act of June 30, 1906.

Approved:

JAMES WILSON,
Secretary of Agriculture.

WASHINGTON, D. C., *October 25, 1906.*

(*F. I. D. 41.*)

APPROVAL OF LABELS.

Numerous requests are referred to this Department for the approval of labels to be used in connection with articles of food and drugs under the food and drugs act of June 30, 1906. This act does not authorize the Secretary of Agriculture nor any agent of the Department to approve labels. The Department therefore will not give its approval to any label. Any printed matter upon the label implying that this

[91] F. I. D. 1-39 practically concern imported foods only and were not issued under the food and drugs act, June 30, 1906.

[92] Page 87.

Department has approved it will be without warrant. It is believed that with the law and the regulations before him the manufacturer will have no difficulty in arranging his label in harmony with the requirements set forth. If there be questions on which there is doubt respecting the general character of labels, decisions under the food and drugs act will be rendered, of a public character and published from time to time, covering such points.

Approved:

JAMES WILSON,
Secretary of Agriculture.

WASHINGTON, D. C., *October 25, 1906.*

(*F. I. D. 42.*)

MIXING FLOURS.

The following communication has been received respecting the mixing of flours of different cereals:

In conformity with the customs of a century or more, the manufacturers of rye flour, in order to produce a lighter and more easily worked flour, have added a proportion of wheat flour to their rye and branded it "Rye Flour."

This custom simply conforms to the customers' demand for a whiter loaf and from every standpoint is a perfectly legitimate operation.

Under the interpretation of the food and drugs act of June 30, 1906, apparent restrictions are placed upon this compounding, and I would therefore respectfully ask your ruling upon the following points:

1. Under this interpretation will it be necessary to add the word "compound" to the brands?

2. Will it be necessary in accordance with this interpretation to name in the brand the fact that a wheat admixture has been made, in addition to the use of the word "compound," providing that word is necessary?

3. Referring to paragraph *f*, Regulation 17,[93] which reads as follows:

> "An article containing more than one food product or active medicinal agent is misbranded if named after a single constituent,"

will it be permissible to still name the rye-wheat admixture "rye flour?"

The food and drugs act of June 30, 1906, and the rules and regulations made thereunder, provide for the proper marking of food products and penalties for misbranding.

The act also provides that a food product is not misbranded "in the case of articles labeled, branded, or tagged so as to plainly indicate that they are compounds, imitations, or blends, and the word 'compound,' 'imitation,' or 'blend,' as the case may be, is plainly stated on the package in which it is offered for sale."[94]

Keeping in view these provisions of the law, and rules and regulations made thereunder, it appears that the mixing of rye flour and wheat

[93] Page 91. [94] Sec. 8, page 79.

flour is not prohibited by the law provided the package is marked "compound" or "mixture," the word standing alone and without qualification, and also if the label contain the information which shows that it is properly branded. The mixture may also be denominated a "blend" if rye flour and wheat flour be regarded as like substances. It is held that this information in the case mentioned would be a statement of the ingredients used in making the compound. It is further held that the use of an ingredient in small quantity simply for the purpose of naming it in the list of ingredients would be contrary to the intent of the law, and therefore that the ingredients must be used in quantities which would justify the appearance of their names upon the label. The statement made of the constituents used should be of a character to indicate plainly that the article is a compound, mixture, or blend.

It is evident from the above explanation that the naming of a mixture of this kind "rye flour" would be plainly a violation of the law and the regulations made thereunder.

Attention is called also to the act of Congress approved June 13, 1898, U. S. Revised Statutes, sections 36 to 49, inclusive, imposing special taxes under the supervision of the Commissioner of Internal Revenue on mixed flour.

Approved:

W. M. Hays,
Acting Secretary.

Washington, D. C., *October 30, 1906.*

(*F. I. D. 43.*)

RELABELING OF GOODS ON HAND.

The following is a type of numerous communications received concerning the operation of the food law:

The retail grocers of our city, as well as some of the jobbers, are very much concerned over stocks of canned goods and other similar goods they might have in stock on January 1, 1907, when the new pure-food act goes into effect.

We are under the impression that where there is nothing deleterious to health contained in such goods so held it is not the Department's intention to interfere in any way, shape, or form with them.

Where these goods are held by retailers in our own city does this come within the jurisdiction of the National law, or it is controlled only by State laws?

Similar letters have been received relating to drugs, medicines, and other articles affected by the operation of the law. A general answer is deemed advisable, which, it is hoped, will cover the cases in question.

Section (i) of Regulation 17[85] provides that—

The regulation regarding the principal label will not be enforced until October 1, 1907, in the case of labels printed and now on hand,

[85] Page 91.

whenever any statement therein contained which is contrary to the food and drugs act, June 30, 1906, as to character of contents, shall be corrected by a supplemental label, stamp, or paster. All other labels now printed and on hand may be used without change until October 1, 1907.

It is held that under this regulation labels which contain statements relating to the name of manufacturer, the place of manufacture, etc., which are not in harmony with the general meaning of the law may be used if on hand on the 1st of January, 1907, the day on which the regulations become effective. Any statement, however, respecting the character of the contents which is false or misleading should be corrected as indicated. The correction should secure the obliteration of the misstatement either by placing the supplemental label or paster over it or obliterating it in some other way. If the goods contain artificial color or preservative other than ordinary condimental substances (salt, sugar, vinegar, wood smoke, spices, and condiments of all kinds), that fact should appear upon the supplemental stamp or paster. If any of the words required to be placed upon drugs and foods in the specific wording of the act do not appear upon the label, such as alcohol, opium, etc., it is held that the correction must include the enumeration of these substances, as provided for in Regulations 28[96] and 29.[97]

If goods that are packed and sealed in a carton which contains the bottle or other package also sealed and labeled were not in the hands of the manufacturer after January 1, 1907, but had been already delivered to the jobber or dealer, it will be held sufficient to mark the external carton alone, provided the goods are sold only in the unbroken carton. If the container, however, holds a large number of separate packages, it will be necessary that each of the separate packages to be sold as such shall be labeled with the words required specifically by the act.

It must not be forgotten that Regulation 17, section (*i*),[98] is for the purpose of avoiding the expense of relabeling articles already packed and branded at the time the regulations go into effect and which necessarily could not have been so packed and branded with any intent to evade the provisions of the law, and it is expected that jobbers and dealers will do everything in their power to bring the packages now on hand into as close harmony with the provisions of the act and the regulations made thereunder as possible.

All articles in the hands of manufacturers, jobbers, and dealers on the 1st day of January, 1907, which are sold wholly within the State in which they are found on that date are exempt from the provisions of the act. Thus the use of the supplemental label, stamp, or paster is required only on those articles which on or after the 1st day of January, 1907, enter interstate commerce or are offered for sale in the District of Columbia and the Territories. It is believed that the provisions of Regulation 17, section (*i*),[98] can be complied with without

[96]Page 96. [97]Page 98. [98]Page 91.

great annoyance and expense. It will be deemed sufficient if the supplemental pasters and labels are attached at the time the goods are shipped beyond the State line, that is, they need not necessarily be attached to such article on the 1st day of January, but at any time thereafter when prepared for interstate commerce. Thus the labor of meeting this requirement will be distributed according to the exegencies of actual trade. On and after October 1, 1907, the labels must be originally properly printed, and no further amendment will be considered.

Approved:
W. M. HAYS,
Acting Secretary.

WASHINGTON, D. C., *November 6, 1906.*

(*F. I. D. 44.*)

SCOPE AND PURPOSE OF FOOD-INSPECTION DECISIONS.

From the tenor of many inquiries received in this Department it appears that many persons suppose that the answers to inquiries addressed to this Department, either in letters or in published decisions, have the force and effect of the rules and regulations for the enforcement of the food and drugs act of June 30, 1906. The following are illustrations of the inquiries received by this Department:

Must we stamp all goods as conforming to the drug and food law, whether they have alcohol and narcotics therein, or not?

On a brand of salad oil, which is a winter-strain cotton-seed oil, can it be sold under the brand of salad oil, or must it state that it is cotton-seed oil?

It seems highly desirable that an erroneous opinion of this kind should be corrected. The opinions or decisions of this Department do not add anything to the rules and regulations nor take anything away from them. They therefore are not to be considered in the light of rules and regulations. On the other hand, the decisions and opinions referred to express the attitude of this Department in relation to the interpretation of the law and the rules and regulations, and they are published for the information of the officials of the Department who may be charged with the execution of the law and especially to acquaint manufacturers, jobbers, and dealers with the attitude of this Department in these matters. They are therefore issued more in an advisory than in a mandatory spirit. It is clear that if the manufacturers, jobbers, and dealers interpret the rules and regulations in the same manner as they are interpreted by this Department, and follow that interpretation in their business transactions, no prosecution will lie against them. It needs no argument to show that the Secretary of Agriculture must himself come to a decision in every case before a prosecution can be initiated, since it is on his report that the district attorney

is to begin a prosecution for the enforcement of the provisions of the act.

In so far as possible it is advisable that the opinions of this Department respecting the questions which arise may be published. It may often occur that the opinion of this Department is not that of the manufacturer, jobber, or dealer. In this case there is no obligation resting upon the manufacturer, jobber, or dealer to follow the line of procedure marked out or indicated by the opinion of this Department. Each one is entitled to his own opinion and interpretation and to assume the responsibility of acting in harmony therewith.

It may be proper to add that in reaching opinions and decisions on these cases the Department keeps constantly in view the two great purposes of the food and drugs act, namely, to prevent misbranding and to prohibit adulteration. From the tenor of the correspondence received at this Department and from the oral hearings which have been held, it is evident that an overwhelming majority of the manufacturers, jobbers, and dealers of this country are determined to do their utmost to conform to the provisions of the act, to support it in every particular, and to accede to the opinions of this Department respecting its construction. It is hoped, therefore, that the publication of the opinions and decisions of the Department will lead to the avoidance of litigation which might arise due to decisions which may be reached by this Department indicating violations of the act, violations which would not have occurred had the opinions and decisions of the Department been brought to the attention of the offender.

JAMES WILSON,
Secretary of Agriculture.

WASHINGTON, D. C., *December 1, 1906.*

(*F. I. D. 45.*)

BLENDED WHISKIES.

Many letters are received by the Department making inquiries concerning the proper method of labeling blended whisky. Manufacturers are anxious to know the construction placed by the Department upon this particular part of the food and drugs act of June 30, 1906, and to ascertain under what conditions the words "blended whisky" or "whiskies" may be used. The following quotation from one of these letters presents a particular case of a definite character:

> On account of the uncertainty prevailing in our trade at the present time as to how to proceed under the pure-food law and regulations regarding what will be considered a blend of whiskies, I am taking the liberty of expressing to you to-day two samples of whisky made up as follows:
>
> Sample A contains 51 per cent of Bourbon whisky and 49 per cent of neutral spirits. In this sample a small amount of burnt sugar is

used for coloring, and a small amount of prune juice is used for flavoring, neither of which increases the volume to any great extent.

Sample B contains 51 per cent of neutral spirits and 49 per cent of Bourbon whisky. Burnt sugar is used for coloring, and prune juice is used for flavoring, neither of which increases the volume to any great extent.

I have marked these packages "blended whiskies" and want your ruling as to whether it is proper to thus brand and label such goods.

My inquiry is for the purpose of guiding the large manufacturing interests in the trade that I represent.

In a subsequent letter from the same writer the following additional statement is made:

The reason for wanting your decision or ruling in this matter is just this: No house in the trade can afford to put out goods and run the risk of seizure and later litigation by the Government on account of the odium that would be attached to fighting the food and drugs act.

The question presented is whether neutral spirits may be added to Bourbon whisky in varying quantities, colored and flavored, and the resulting mixture be labeled "blended *whiskies*." To permit the use of the word "whiskies" in the described mixture is to admit that flavor and color can be added to neutral spirits and the resulting mixture be labeled "whisky." The Department is of opinion that the mixtures presented can not legally be labeled either "blended whiskies" or "blended whisky." The use of the plural of the word "whisky" in the first case is evidently improper for the reason that there is only one whisky in the mixture. If neutral spirit, also known as cologne spirit, silent spirit, or alcohol, be diluted with water to a proper proof for consumption and artificially colored and artificially flavored, it does not become a whisky, but a "spurious imitation" thereof, not entirely unlike that defined in section 3244, Revised Statutes. The mixture of such an imitation with a genuine article can not be regarded as a mixture of like substances within the letter and intent of the law.

JAMES WILSON,
Secretary of Agriculture.

WASHINGTON, D. C., *December 1, 1906.*

(*F. I. D. 46.*)

FICTITIOUS FIRM NAMES.

The following extract from a letter is typical of a question frequently asked:

In connection with our manufacture of flavoring extracts, we produce an article containing a certain percentage of artificial coumarin and vanillin. This product has been placed on the market under the name of ——— and Company, a fictitious firm, although dealers have always understood that it was our product. Is there any objection to our continuing to brand the product as manufactured by ——— and Company?

The same question has frequently been asked by importers who state that they desire to assume the responsibility for particular brands.

It has been held by the Attorney-General (F. I. D. 2) that—

the words " * * * Daisy Sugar Corn, ——— ——— Company, Milwaukee, Wis.," clearly imply that the goods referred to are manufactured or prepared by that company in Wisconsin. The general public, unfamiliar with trade practices, would inevitably reach that conclusion.

Regulation 18[99] provides that if the name of the manufacturer and the place of manufacture be given, they must be the true name and the true place. It would appear, therefore, that the use of a fictitious name in such a manner that it would be understood to be the name of the manufacturer would be clearly a violation of Regulation 18.[99] It is apparent that the provisions of Regulation 18[99] will not be fulfilled by the nominal incorporation of a fictitious firm. The regulations require that goods must be actually manufactured by the firm represented on the label as the manufacturer.

When a proper name, other than that of the manufacturer, is placed upon a label it must not be used in the possessive. For instance,

CHARLES GASTON'S
OLIVE OIL
BORDEAUX

can only be properly used on an oil manufactured by Charles Gaston at Bordeaux. The same is true if the designation

GASTON'S
OLIVE OIL
BORDEAUX

be employed.

On the other hand, the word "Gaston" might be used in an adjective sense, and not in the possessive case as qualifying the words "olive oil," in a manner that would indicate that it represented a brand and not a manufacturer, as

GASTON OLIVE OIL.

In such case, however, neither given name nor initials should be employed. The word "Gaston" should be in the same type as "olive oil" and in equal prominence, thus forming a part of the label. Again, "Gaston," or "Charles Gaston," might be used accompanied by the word "Brand," as,

OLIVE OIL
GASTON BRAND.

Or,

OLIVE OIL
CHARLES GASTON BRAND.

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[99]Page 92.

In such cases, however, the name of the manufacturer should also be given.

JAMES WILSON,
Secretary of Agriculture.

WASHINGTON, D. C., *December 13, 1906.*

(*F. I. D. 47.*)

FLAVORING EXTRACTS.

The percentage of alcohol is not required to be stated in the case of extracts sold for the preparation of foods only. It is held, however, that extracts which are sold or used for any medicinal purpose whatever should have the percentage of alcohol stated on the label.

Numerous inquiries are received regarding the proper designation of products made in imitation of flavoring extracts or in imitation of flavors. Such products include "Imitation vanilla flavor," which is made from such products as tonka extract, coumarin, and vanillin, with or without vanilla extract. They may also include numerous preparations made from synthetic fruit ethers intended to imitate strawberry, banana, pineapple, etc. Such products should not be so designated as to convey the impression that they have any relation to the flavor prepared from the fruit. Even when it is not practicable to prepare the flavor directly from the fruit, "imitation" is a better term than "artificial."

These imitation products should not be designated by terms which indicate in any way by similarity of name that they are prepared from a natural fruit or from a standard flavor. The term "venallos," for instance, would not be a proper descriptive name for a preparation intended to imitate vanilla extract. Such products should either be designated by their true names, such as "vanilla and vanillin flavor," "vanillin and coumarin flavor," or by such terms as "imitation vanilla flavor," or "vanilla substitute."

Articles in the preparation of which such substitutes are employed should not be labeled as if they were prepared from standard flavors or from the fruits themselves. For instance, ice cream flavored with imitation strawberry flavor should not be designated as "strawberry ice cream." If sold as strawberry ice cream without a label the product would appear to be in violation of Regulation 22.[100]

Artificial colors should be declared whenever present.

JAMES WILSON,
Secretary of Agriculture.

WASHINGTON, D. C., *December 13, 1906.*

[100] Page 94.

(*F. I. D. 48.*)

SUBSTANCES USED IN THE PREPARATION OF FOODS.

The following letter was recently received at the Department of Agriculture:

We import a preparation of gelatin preserved with sulphurous acid for the purpose of fining wine. This gelatin is not used as a food and does not remain in the wine, although a small amount of the sulphurous acid may be left in the wine. Please inform us if the sale of this product is a violation of the food law.

It is held that the products commonly added to foods in their preparation are properly classed as foods and come within the scope of the food and drugs act. The Department can not follow a food product into consumption in order to determine the use to which it is put. Pending a decision on the wholesomeness of sulphurous acid as provided in Regulation 15 (*b*),[1] its presence should be declared.

JAMES WILSON,
Secretary of Agriculture.

WASHINGTON, D. C., *December 13, 1906.*

(*F. I. D. 49.*)

TIME REQUIRED TO REACH DECISIONS ON DIFFERENT PROBLEMS CONNECTED WITH THE FOOD AND DRUGS ACT, JUNE 30, 1906.

Many letters have reached the Department asking for action on very important questions connected with the food and drugs act which require much study and time to secure all the facts necessary to the rendering of a just decision. It is quite impossible to answer all such letters in detail. The following general statement shows the attitude of the Department on questions of this kind:

All manufacturers and dealers have copies of the law and regulations or can secure them and study them carefully. Each manufacturer and dealer should conduct his business as nearly as possible in harmony with the law as he interprets it. When each particular problem involved reaches a solution in this Department, it is hoped it will be found that the manufacturers and jobbers have come also to a similar decision in the matter. Public notice will be given of each decision as it is issued, that the manufacturers and dealers may be informed and be able at once to place themselves in line with the decisions of the Department. In this way it is hoped that all injustice will be avoided in the execution of the law and everyone be given an opportunity to put himself right and to have due notice of decisions which may be made.

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[1] Page 89.

The Department will use every endeavor to reach prompt decisions, but must take time to collect the facts and subject them to a proper study; otherwise the decisions would not have the value which should attach to them in important matters affecting the execution of the law.

JAMES WILSON,
Secretary of Agriculture.

WASHINGTON, D. C., *January 8, 1907.*

(*F. I. D. 50.*)

IMITATION COFFEE.

A manufacturer writes as follows:

We beg to ask for your opinion as regards the hyphenated word "Cereal-Coffee," and whether or not we are entitled to its use for a cereal substitute for coffee. * * * In our opinion the term "Cereal-Coffee" would come under the so-called trade name and distinctive name.

It is held that since the product mentioned is not a coffee it can not properly be called by the term mentioned. Regulation 20 (d)[2] provides that a distinctive name shall give no false indication of character. The use of the name "cereal-coffee" might be taken to indicate that the product is coffee or has the properties of coffee, and hence the use of this term does not comply with the definition of distinctive name. Even if the product consist in part of coffee, the name would not be correct. It is suggested that products of this nature be designated as "imitation coffee," as provided in Regulation 21 (f).[3] In such case the word "imitation" should be in uniform type, on uniform background, and should be given equal prominence with the word "coffee."

JAMES WILSON,
Secretary of Agriculture.

WASHINGTON, D. C., *January 18, 1907.*

(*F. I. D. 51.*)

COLORING OF BUTTER AND CHEESE.

Numerous inquiries, of which the following is an illustration, have been received by the Department:

Will you kindly inform me concerning the coloring of butter and cheese under the pure-food law? Would it be unlawful to color butter and cheese as now practiced?

The coloring of butter is specifically permitted in the law of August 2, 1886 (24 Stat., 209), and the coloring of cheese in the law of June 6, 1896 (29 Stat., 253). It is held by the Department that the

[2] Page 93. [3] Page 94.

food and drugs act does not repeal the provisions of the acts referred to above and the addition of harmless color to these substances may be practiced as therein provided, and that the presence of coloring matter specifically recognized by acts of Congress as a constituent is not required to be declared on the label.

JAMES WILSON,
Secretary of Agriculture.

WASHINGTON, D. C., *January 18, 1907.*

(*F. I. D. 52.*)

FORM OF LABEL.

The following is an extract from a letter recently received:

We do not understand the requirements of the regulations respecting the arrangement of labels; that is, the order in which the various features of the label should be arranged.

To meet the requests for the opinion of the Department regarding the proper arrangement of a label, the following order is suggested:

1. Name of substance or product.

2. In case of foods, words which indicate that the articles are compounds, mixtures, or blends, and the word "Imitation," "Compound," or "Blend," as the case may be.

3. Statements designating the quantity or proportion of the ingredients enumerated in the law, or derivatives and preparations of same[a] as mentioned under Regulation 28;[3] also statements of other extraneous substances whose presence should be declared, such as harmless coloring matter, or any necessary statement regarding grade or quality.

(The statements specified in paragraphs 1, 2, and 3, should appear together without any intervening descriptive or explanatory matter.)

4. Name of manufacturer (if given).

5. Place of manufacture (if given, or when required in case of food mixtures or compounds bearing a distinctive name).

It is stated in Regulation 17[4] that if the name of the manufacturer and place of manufacture be given they should appear upon the principal label. Although the law does not require that the name of the manufacturer be given, or the place of manufacture, except in case of food mixtures and compounds having a distinctive name, it is held that if they are given they must be true, and should be placed with the required information on the principal label. The arrangement of the label is the same for both food and drug products and an example of each is given.

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[a] Attention is called to the fact that the declaration of alcohol and its derivatives is not required in foods.

[3] Page 96. [4] Page 90.

Sample label for food product.

[Name of product.]

[Declaration required by paragraphs 2 and 3.]

KETCHUP.

ARTIFICIALLY COLORED.

[Descriptive matter, if desired, but preferably at bottom of label.]

[Name of manufacturer, if given.]

[Place of manufacture, if given.]

BLANK & CO.,

PORTLAND, ME.

[Descriptive matter, if desired.]

Sample label for drug product.

[Name of product.]

[Declarations required by paragraphs 2 and 3.]

COUGH SYRUP.

ALCOHOL, 10 PER CENT.
MORPHINE, ½ GRAIN PER OUNCE.
CHLOROFORM, 40 MINIMS PER OUNCE.

[Descriptive matter, if desired, but preferably at bottom of label.]

[Name of manufacturer, if given.]

[Place of manufacture, if given.]

JOHN JONES & CO.,

WASHINGTON, D. C.

[Descriptive matter, if desired.]

Any descriptive or explanatory matter that may appear on the principal label, therefore, should be placed at the bottom of the label, or between No. 3 and No. 4, and should be clearly separated from other features of the label by means of a suitable line or space. Statements regarding the reason for using alcohol, artificial coloring matter, and other extraneous substances, come under the head of descriptive or explanatory matter, and should not be interspersed with the declarations required under Nos. 2 and 3.

The information called for under No. 3 should not be so worded as to give only the required information, as, for example, "alcohol 17 per cent" or "artificially colored." All numbers used in expressing quantity or proportion of substances required to be stated (see Regulation 28[5]) should be expressed in the Arabic notation.

Each substance required to be declared under No. 3 should be

[5] Page 96.

printed on a separate line and in type specified in Regulation 17 (c).[6]

JAMES WILSON,
Secretary of Agriculture.

WASHINGTON, D. C., *January 18, 1907.*

(*F. I. D. 53.*)

FORMULA ON THE LABEL OF DRUGS.

Many inquiries are received relative to the necessity of giving the formula of medicinal remedies on the label. The following is typical:

I should like to know if it will be necessary for me to state on a label the name of the products from which I prepare my proprietary medicine in order to conform with the pure food and drugs act. If I do this, it will prohibit me from manufacturing and selling a remedy which is a secret of my own; and anyone buying it could, from the label, tell what ingredients were used in its preparation and make his own supply of this medicine. How does the United States Government expect to protect those who have secret medicinal preparations they wish to sell at a profit? If the Pure Food Commission desires, I will send them a sample bottle of my medicine for their inspection and approval.

The food and drugs act, June 30, 1906, does not require the formula of drug products to be given on the label, but requires only that the quantity or proportion of the ingredients enumerated in the law, and derivatives and preparations of same (Regulation 28),[7] shall be clearly set forth on the label or labels of all preparations used for the treatment or prevention of disease, either internally or externally, for man or other animals. This includes sample packages as well as regular trade packages.

The question is also frequently asked whether a medicinal preparation would be exempt from the operation of the law if the formula were given on the label. The formula on the label is very desirable, but this information is not required by the law. The act forbids the use of any statement, design, or device in connection with any drug product which is false or misleading in any particular. A defect of this kind would not be corrected by giving the formula on the lable. If the formula is given, it must be the correct and complete formula. It is held that, in addition to those substances required by the act to be named, if only a part of the active medinical agents used in the manufacture of a drug product are set forth on the label, such a procedure is misleading and therefore forbidden by the law. All drug products and their labels must conform to the act, whether the formula is or is not given on the label.

JAMES WILSON,
Secretary of Agriculture.

WASHINGTON, D. C., *January 28, 1907.*

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[6] Page 91. [7] Page 96.

(*F. I. D. 54.*)

DECLARATION OF THE QUANTITY OR PROPORTION OF ALCOHOL PRESENT IN DRUG PRODUCTS.

The question of stating the percentage of alcohol present in drug products has caused a multitude of inquiries. The following questions along this line serve as examples:

Is it necessary to give the amount of alcohol present in U. S. Pharmacopœial or National Formulary products? It seems to me that such a requirement is absurd, and not contemplated within the spirit of the act. None of them are patent medicines. Will I be compelled to tell how much alcohol is present in such goods?

If we apply for and obtain a serial number, must we in addition to putting this number on our labels state the per cent of alcohol?

Will it be necessary to give the per cent of alcohol present in such products as ether, chloroform, collodion, spirit of nitrous ether, and similar preparations?

The law is specific on the subject of declaring the amount of alcohol present in medicinal agents, as can readily be seen from the following language: "An article shall also be deemed misbranded * * * if the package fail to bear a statement on the label of the quantity or proportion of any alcohol * * * contained therein." No medicinal preparations are exempt, whether they are made according to formulæ given in the U. S. Pharmacopœia or National Formulary or formulæ taken from any other source. The serial number, with or without the guarantee legend, does not exempt a preparation from this requirement. The law does not make any statement as to the amount of alcohol that may or may not be employed. It requires, however, that whatever amount be present shall be set forth on the label. The percentage of alcohol given on the label should be the percentage of absolute alcohol by volume contained in the finished product. The manner in which it should be printed is shown in F. I. D. 52.

JAMES WILSON,
Secretary of Agriculture.

WASHINGTON, D. C., *March 13, 1907.*

(*F. I. D. 55.*)

METHOD OF STATING QUANTITY OR PROPORTION OF PREPARATIONS (CONTAINING OPIUM, MORPHINE, ETC.) USED IN MANUFACTURING OTHER PREPARATIONS.

Many inquiries are received as to the method of stating the quantity or proportion of preparations (containing opium, morphine, etc.) used in the manufacture of other preparations. Of these the following are typical:

If the label on the bottle were to bear the words "Tincture of Opium." I reason that as this is a definite preparation, constituting a preparation of opium, and so definite as to its composition that to any intelligent person it expresses definitely all that it is desirable to express, the use of this title alone should be sufficient. I feel that as a preparation it is distinct from opium, and if this particular tincture is used in the manufacture of a preparation the mention of it alone should be sufficient.

Where extract or tincture of cannabis indica, or extract of opium, is employed in making other drug products, would it not be complying with the law if the use of such articles be clearly indicated on the label as prescribed by the law, or is it necessary to give the actual amounts of the drugs themselves represented by these preparations?

Names of drug products bearing any of the names of the ingredients enumerated in the act are construed as representing "preparations" within the meaning of the act; and if the same are clearly declared upon the label as required by Regulations 17[8] and 30,[9] it will not be necessary to give the actual amount of the primary drugs used or represented by such article. It is desirable, however, that the word or words used in the law shall constitute the first part of the name of the product. For example: "Opium, Tincture of;" "Cannabis Indica, Extract of," followed by the amount of tincture or extract used.

JAMES WILSON,
Secretary of Agriculture.

WASHINGTON, D. C., *March 13, 1907.*

(*F. I. D. 56.*)

NAMES TO BE EMPLOYED IN DECLARING THE AMOUNT OF THE INGREDIENTS AS REQUIRED BY THE LAW.

Many inquiries are coming to this Department relative to the names that may be employed in declaring the quantity or proportion of the ingredients, as required by Congress.

The following are representative:

The word "alcohol" has received so much unfavorable notoriety during the last few years that we hesitate to place it upon our labels. Could we not employ some other words in place of it, such as "cologne spirits," "spirits of wine," "pure grain alcohol," etc.?

Would it be satisfactory for us to use "Phenylacetamide," or the following formula, C_6H_5 (CH_3CO), for the chemical acetanilide?

One of our preparations contains trichlorethidene ethyl alcoholate, which would undoubtedly under the law be considered a derivative of chloral hydrate. Will it be satisfactory for us to use this name on our trade packages in giving the amount of this chemical present in the product?

In the manufacture of some of our products we use opium. It would, however, be a financial loss to state this fact on the label. Could we not say this preparation contains 20 grains of the concentrated extract of the *Papaver somniferum* to the fluid ounce?

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[8]Page 90. [9]Page 98.

Dover's powder is mentioned in the regulations as one of the preparations of opium. It would seem sufficient at first glance that Dover's powder as a preparation, if mentioned on the label, would be all that could be required as to opium.

One of the objects of the law is to inform the consumer of the presence of certain drugs in medicines, and the above terms do not give the average person any idea as to the presence or absence of such drugs. In enumerating the ingredients, the quantity or proportion of which is required to be given upon the principal label of any medicinal preparation in which such ingredients may be present, the act uses only common names, and the permission to use any but such common names for any ingredients required to be declared upon the label is neither expressed nor implied in any part of the law.

The term used for acetanilide is "acetanilide" and not phenlyacetamide. No reference is made to the use of the chemical formula in designating the presence of chemicals. The words "chloral hydrate" appear in the act, but not the chemical name trichlorethidene glycol. It can readily be seen that if the act were not closely adhered to in this connection there would soon be such a confusion and multiplicity of names and phrases that one of the objects of the act would be defeated.

The names to be employed in stating the quantity or proportion of the ingredients required by the act to appear on the label of all medicinal preparations containing same are—

First. Those used in the law for the articles enumerated; example, "alcohol," not "spiritus rectificatus."

Second. In the case of derivatives: (*a*) The name of the parent substance used in the act should constitute part of the name; example, "chloral acetone," not "trichlorethidene dimethyl ketone." (*b*) The trade name, accompanied in parenthesis by the name of the present substance; example, "dionine (morphine derivative)."

Third. Names of preparations containing the name of some ingredient used in the act. In such cases the name used in the act should constitute the first portion of the name of the preparation. (See F. I. D. 55.[19])

Fourth. Common names (such as laudanum, Dover's powder, etc.) of preparations containing an ingredient enumerated in the law, provided such name or names are accompanied in parentheses by some such phrase as "preparation of opium" or "opium preparation," followed by the number of minims or grains, as specified in the regulations; for instance, "laudanum (preparation of opium), 40 minims per ounce."

JAMES WILSON,
Secretary of Agriculture.

WASHINGTON, D. C., *March 13, 1907.*

[19] Page 120.

(*F. I. D. 57.*)

PHYSICIANS' PRESCRIPTIONS.

The Status of Packages Compounded According to Physicians' Prescriptions and Entering Into Interstate Commerce.

Packages resulting from the compounding of physicians' prescriptions under the food and drugs act are the subject of many queries, of which the following are representative:

If a druggist compounds a physicians' prescription and sends it into an adjoining State, will it be necessary to state upon the label the amount of alcohol, morphine, etc., that may be present?

Supposing a regularly licensed practicing physician has patients located in various States of the Union and supplies medicines to them through the mails, by express, and otherwise, do such packages come under the provisions of the law, and, if so, can the required information be given in pen and ink on the label?

We treat drug addictions on a very gradual tonic treatment reduction plan. For instance, if John Doe writes for information as to the home treatment for his addiction, I send him a symptom blank which contains, among other questions, an inquiry as to the kind of drug he uses, how he uses it, the length of time he has used it, etc. In addition to giving me a complete history of his case, he states he is using 10 grains of sulph. of morphine (each twenty-four hours), hypodermically or internally, as the case may be. In prescribing in his case I immediately put him on just one-half of the amount he reports as his daily allowance, combining same with a bitter tonic.

It is necessary for the reduction in drug cases to be made without the patient's knowledge. It is, of course, understood by all physicians that you can not trust a drug habitué to properly make his own reductions, for, as a matter of fact, if he knew to what extent I was reducing his daily allowance of opiates, he would imagine the reduction too rapid, he would get frightened, and would take to his former drug for relief. Treatment prepared in this way I do not think would come under the head of a proprietary preparation or a patent medicine, as I prescribe the contents of each bottle to meet the requirements of each individual patient. All instructions as to the conduct of treatment and the use of auxiliary remedies are given by letter; consequently there are no printed labels or cartons containing any claims concerning the efficacy of this treatment.

I would be pleased to have you inform me whether in your opinion I would be violating the pure-food law in any manner, shape, or form should I continue to label my preparations as I am now doing, and in having them prepared in ——— and forwarded direct to my patients in this and other States.

If a package compounded according to a physician's prescription be shipped, sent, or transported from any State or Territory or the District of Columbia to another State or Territory or the District of Columbia by a compounder, druggist, physician, or their agents, by mail, express, freight, or otherwise, the label upon such package is required to bear the information called for by Congress. If, however, the patient himself, or a member of his household, or the physician himself carries such package across a State line, and such package

is not subject to sale, it is held that such package need not be marked so as to conform with the law, because such a transaction is not considered one of interstate commerce.

The package may be marked so as to comply with the act by either stamp, pen and ink, or typewriter, provided all such written matter is distinctly legible and on the principal label, as prescribed in Regulation 17.[11]

JAMES WILSON,
Secretary of Agriculture.

WASHINGTON, D. C., *March 13, 1907.*

(*F. I. D. 58.*)

THE LABELING OF PRODUCTS USED AS FOODS AND DRUGS AS WELL AS FOR TECHNICAL AND OTHER PURPOSES.

Frequent requests for information relative to the proper labeling of products bearing the names of foods and drugs, but used also for technical and other purposes, are received. The following are typical:

We will kindly ask you to advise us in regard to the new law that governs the line of oils. We manufacture a compound product, so-called "turpentine," which contains pure turpentine and a very fine petroleum product. It is used in most branches where pure turpentine is used, with the exception of medicinal purposes, for which we do not sell it.

We understand that if we were to sell any cotton-seed oil so branded as to indicate that it was intended to be used as a food, as, for example, under the brand "Blank Salad Oil," it would be necessary to observe the requirements of the law referred to; but we are in doubt and would be glad to have your opinion as to whether a sale or shipment of this oil (for lubricating purposes) under the ordinary trade brand of cotton-seed oil, and without anything to indicate that it was of a quality suitable for use as a salad oil, would subject us to the provisions of the act.

During personal interviews the question of marking chemical reagents has also been discussed.

Products used in the arts and for technical purposes are not subject to the food and drugs act. It is, however, a well-recognized fact that many articles are used indiscriminately for food, medicinal, and technical purposes. It is also well known that some products employed for technical purposes are adulterated or misbranded within the meaning of this act. Inasmuch as it is impossible to follow such products into consumption in order to determine to what use they are finally put, it is desirable that an article sold under a name commonly applied to such article for food, drug, and technical purposes be so labeled as to avoid possible mistakes. The ordinary name of a pure and normal product, whether sold for food, drug, technical, or other purposes, is all that is necessary. Pure cotton-seed oil or turpentine may be sold without any restrictions whatever, whether such article is sold for food, medicinal, or technical purposes, but it is suggested that a cotton-

[11] Page 90.

seed oil intended for lubricating purposes, or a so-called turpentine consisting of a mixture of turpentine and petroleum oils, used by the paint trade, be plainly marked so as to indicate that they are not to be employed for food or medicinal purposes. Such phrases as the following may be used: "Not for Food Purposes," "Not for Medicinal Use," or for "Technical Purposes Only," or "For Lubricating Purposes," etc.

In order to avoid complication it is suggested that chemical reagents sold as such be marked with such phrases as the following: "For Analytical Purposes," or "Chemical Reagent," etc.

JAMES WILSON,
Secretary of Agriculture.

WASHINGTON, D. C., *March 13, 1907.*

(*F. I. D. 59.*)

NATIONAL FORMULARY APPENDIX.

The National Formulary is one of the standards recognized under the law. The question has been asked a number of times whether the appendix of this authority would be construed as part and parcel of the book itself. On page IV of the preface it is distinctly stated that the formulæ collected in the appendix of the National Formulary are "no longer designated as 'N. F.' preparations." This shows that these formulæ are not integral parts of the book under the law, which covers only those products of the National Formulary recognized as such by this authority. By this it is understood that if a drug product is sold under a name contained in the appendix of the National Formulary, it will not be necessary for such product either to conform to the standard indicated by the formula or to declare upon the label its own standard strength, quality, and purity if a different formula is employed in its manufacture. Such articles are, however, subject to the law in every other respect, as is the case of other medicinal products not recognized by the U. S. Pharmacopœia or National Formulary.

JAMES WILSON,
Secretary of Agriculture.

WASHINGTON, D. C., *March 13, 1907.*

(*F. I. D. 60.*)

MINOR BORDER IMPORTATIONS.

Inquiry has frequently been made regarding the application of Regulation 33[1] (requiring a declaration to be attached to the invoice) to foods and drugs brought into the United States in small quantities by farmers living near the border. One correspondent says:

Farmers along the border are in the habit of occasionally bringing in, in their own teams, maple sugar in small quantities, also butter and

[1] Page 100.

like articles of food products of their own raising, and offering the same for entry at the different offices on the frontier. * * * The main question is as to whether or not the affidavits and other proof required by the pure-food law shall be required in these instances of minor importations of this class of articles.

Considering the nature of these importations it is held that Regulation 33[1] does not apply to them and that they may be imported without the declaration. Such products are subject to inspection, however, and if found to be in violation of the law will be excluded.

JAMES WILSON,
Secretary of Agriculture.

WASHINGTON, D. C., *March 25, 1907.*

(*F. I. D. 61.*)

COCOA BUTTER SUBSTITUTES.

A manufacturer writes:

We use in the preparation of chocolate sticks a guaranteed pure production of cocoanut oil. May this product be sold merely as confectionery, and not as chocolate sticks? If not, would it be satisfactory for us to mark the product as "Chocolate sticks prepared with substitute butter?"

Regulation 22 prohibits the sale, or offer for sale, in interstate or foreign commerce or in the District of Columbia or in any Territory of the United States, of a food or drug product which bears no label whatever if said product be an imitation of or offered for sale under the name of another article. It would clearly be a violation of the law to sell an article which was made in imitation of chocolate, even though it be sold under the general name of a confection. Such an article should be labeled in such manner as to correctly represent its true nature.

Regulation 25 (*a*)[2] provides:

When a substance of a recognized quality commonly used in the preparation of a food or drug product is replaced by another substance not injurious or deleterious to health, the name of the substituted substance shall appear upon the label.

It is held that cocoa butter is the only fat that can properly be used in chocolate. The declaration of foreign fats merely as "substitute butter" is apparently not sufficient; the nature of the fat employed should be stated.

JAMES WILSON,
Secretary of Agriculture.

WASHINGTON, D. C., *March 25, 1907.*

[1]Page 100. [2]Page 95.

(*F. I. D. 62.*)

GUARANTY ON IMPORTED PRODUCTS.

Many inquiries of the following type have been received by the Department:

We will take it as a favor if you will advise us if (since our goods are all imported and so must pass the custom-house before being sold) the fact of their having passed the customs authorities and the Department of Agriculture examination is not in itself a guaranty that they conform with the pure-food laws as defined by the act of Congress approved June 30, 1906, entitled "An act for preventing the manufacture, sale or transportation of adulterated or misbranded or poisonous or deleterious foods, drugs, medicines, liquors," etc.

The Department makes a systematic inspection of imported foods and drugs when they arrive at the custom-houses; and while such inspection does not include an examination of samples taken from every package of the aforesaid articles, it is sufficient to indicate that the article is suitable to enter the country and be sent into interstate commerce as long as it retains its identity in the unbroken package. If imported foods and drugs are taken from the original packages and repacked, they become subject to inspection as if of domestic origin, and the persons handling and selling said articles are not immune from prosecution in the event that a subsequent inspection discloses that all or any portion of said foods or drugs are adulterated or misbranded according to the provisions of said statute or the regulations made thereunder.

Only a wholesaler, jobber, manufacturer, or other party residing in the United States can give a guaranty within the meaning of said act. A foreign manufacturer or other foreign dealer can not give the guaranty prescribed in said law, nor can the agent of such foreign manufacturer or dealer give said guaranty unless such agent be a resident of the United States and unless he actually sells the goods covered by the guaranty.

The person who owns and sells imported goods can make a guaranty for the purpose aforesaid, though the goods may be shipped directly by the firm of whom the guarantor buys them to the customer of the guarantor.

JAMES WILSON,
Secretary of Agriculture.

WASHINGTON, D. C., *March 25, 1907.*

(*F. I. D. 63.*)

USE OF THE WORD "COMPOUND" IN NAMES OF DRUG PRODUCTS.

Many inquiries are received concerning the use of the word "compound" in names of drug products. There seems to be a general

impression that this word can be applied as a corrective to many misbranded products. The following extracts serve as examples:

You have on file our formula (active agents—croton oil and cascara), and we would ask if it is possible to call the same "castor pill compound" and comply with the regulations.

This liniment has been in use for forty years. The ingredients, each separately and collectively, are sanitary and highly curative. The one ingredient after which it was named happens to be present in the least proportion; can not the compound be called by the name "Compound Sassafras Cream?"

An eminent jurist writes:

I shall be glad to know the views entertained by your Department as to when a druggist has satisfied this act by a label or printed matter which he puts on the package or bottle in relation to a compound. Take, for example, the product put on the market as Cascarin Compound, or Aloin Compound. I am impressed with the fact that such label must have added a statement as to what the other ingredients of the compound are. This may not mean, and probably does not mean, that the formula must be given or the exact proportions, but a purchaser has the right to know what is in the compound in order to determine for himself, or to receive proper advice, as to whether it is safe to be used.

In no case can a preparation be named after an ingredient or drug which is not present. The word "compound" should not be used in connection with a name which in itself, or together with representations and designs accompanying same, would be construed as a form of misbranding under the act.

It is held that if a mixture of drugs is named after one or more but not all of the active medicinal constituents (not vehicle) present in a preparation, the word "compound" can be used in connection with the name, (*a*) provided the active constituent after which the product is named is present in an amount at least equal to that of any other active medicinal agent present. Example: If it is desired to make a mixture consisting of oil of sandalwood, balsam copaiba, and castor oil, and call this product "Oil of Sandalwood Compound," the oil of sandalwood should constitute at least 33 1-3 per cent of the entire mixture. Or (*b*) provided the potent active constituent after which the product is named is present in sufficient amount to impart the predonderating medicinal effect. Example: If a product is named after the active constituent, strychnine, the strychnine or one of its salts should be present in sufficient amount to produce the preponderating medicinal effect of the preparation. Or (*c*) provided the complete quantitative formula, as outlined in the United States Pharmacopœia and National Formulary, be given on the principal label. A declaration of the complete quantitative formula, however, does not exempt the manufacturer or dealer from giving the information required by the act in the manner prescribed by the regulations. The

ounce shall be the unit. The amounts of the ingredients present (excepting alcohol, which is to be stated in per cent) shall be given in grains or minims, and if it is desired the metric equivalent may be given in addition.

JAMES WILSON,
Secretary of Agriculture.

WASHINGTON, D. C., *March 23, 1907.*

(*F. I. D. 64.*)

LABELING OF SARDINES.

Many inquiries have been made of this Department respecting the extent to which the term "sardine" can be used in food products entering into foreign or interstate commerce. The question of the proper labeling of fish of this kind was submitted by the Department to the Department of Commerce and Labor, Bureau of Fisheries. After reviewing the nomenclature and trade practices the Department of Commerce and Labor reached the following conclusion:

Commercially the name sardine has come to signify any small, canned, clupeoid fish; and the methods of preparation are so various that it is impossible to establish any absolute standard of quality. It appears to this Department that the purposes of the pure-food law will be carried out and the public fully protected if all sardines bear labels showing the place where produced and the nature of the ingredients used in preserving or flavoring the fish.

In harmony with the opinion of the experts of the Bureau of Fisheries, the Department of Agriculture holds that the term "sardine" may be applied to any small fish described above, and that the name "sardine" should be accompanied with the name of the country or State in which the fish are taken and prepared, and with a statement of the nature of the ingredients used in preserving or flavoring the fish.

It is held that a small fish of the clupeoid family, caught upon or near the shores of and packed in oil in Norway, or smoked and packed, in oil, is properly labeled with the phrase "Norwegian Sardines in Oil," or "Norwegian Smoked Sardines in Oil," the nature of the oil being designated. In like manner a small fish of the clupeoid family caught upon or near the shores of and packed in France may be called "French Sardines in Oil," the nature of the oil being specified. Following the same practice, a fish of the clupeoid family caught on or near the shores of and packed in the United States may be labeled "American Sardines Packed in Oil," or "Maine Sardines Packed in Oil," or be given some similar appellation, the nature of the oil being stated. It is suggested that the name of the particular

fish to which the term sardine is to be applied should also be placed upon the label—for example, "Pilchard," "Herring," etc.

JAMES WILSON,
Secretary of Agriculture.

WASHINGTON, D. C. *March 29, 1907.*

(*F. I. D. 65.*)

THE LABELING OF WHISKY, BLENDS, COMPOUNDS, AND IMITATIONS THEREOF.

The labeling of whisky, blends, compounds, and imitations thereof, under the food and drugs act of June 30, 1906, will be governed by the opinion of the Attorney-General, dated April 10, 1907, bearing the approval of the President, published herewith.

JAMES WILSON,
Secretary of Agriculture.

WASHINGTON, D. C., *April 11, 1907.*

THE WHITE HOUSE,
WASHINGTON, D. C., *April 10, 1907.*

MY DEAR MR. SECRETARY:

In accordance with your suggestion, I have submitted the matter concerning the proper labeling of whisky under the pure-food law to the Department of Justice. I enclose the Attorney-General's opinion. I agree with this opinion and direct that action be taken in accordance with it.

Straight whisky will be labeled as such.

A mixture of two or more straight whiskies will be labeled "Blended whisky" or "whiskies."

A mixture of straight whisky and ethyl alcohol, provided that there is a sufficient amount of straight whisky to make it genuinely a "mixture," will be labeled as compound of, or compounded with, pure grain distillate.

Imitation whisky will be labeled as such.

Sincerely, yours,

THEODORE ROOSEVELT.

Hon. JAMES WILSON,
Secretary of Agriculture.

OPINION OF THE ATTORNEY-GENERAL.

APRIL, 10, 1907.

The President.

SIR: In accordance with your instructions, I have examined the papers referred to me by you, at the suggestion of the Secretary of Agriculture, and herewith submit you my opinion on certain questions which appear from the said papers to have arisen in connection with the labeling or branding of different kinds of spirit, claimed by

their manufacturers or proprietors to be entitled to the name of "Whisky," with or without qualifying words. In addition to the papers referred to me by you, I have received and considered a number of other papers submitted to me by various individuals, including Messrs. Hemphill and Worthington and Mr. W. M. Hough, as counsel for certain distillers and rectifiers interested in the questions under consideration, and I have personally gathered some further information which seemed to me material in view of the character of the questions involved.

These questions have arisen in the construction of section 8[1] of the act approved June 30, 1906, entitled:

"An act for preventing the manufacture, sale, or transportation of adulterated or misbranded or poisonous or deleterious foods, drugs, medicines, and liquors, and for regulating traffic therein, and for other purposes,"

and generally known as "The pure food law." The portion of that law bearing upon the points in dispute is section 8, which, so far as material, is as follows:

SEC. 8.[1] That the term "misbranded," as used herein, shall apply to all drugs, or articles of food, or articles which enter into the composition of food, the package or label of which shall bear any statement, design, or device regarding such article, or the ingredients or substances contained therein, which shall be false or misleading in any particular. * * * That for the purposes of this act an article shall also be deemed to be misbranded: * * * In the case of food: First. If it be an imitation of or offered for sale under the distinctive name of another article. * * * Fourth. If the package containing it or its label shall bear any statement, design, or device regarding the ingredients or the substances contained therein, which statement, design, or device shall be false or misleading in any particular: *Provided,* That an article of food which does not contain any added poisonous or deleterious ingredients shall not be deemed to be adulterated or misbranded in the following cases:

First. In the case of mixtures or compounds which may be now or from time to time hereafter, known as articles of food, under their own distinctive names, and not an imitation of or offered for sale under the distinctive name of another article, if the name be accompanied on the same label or brand with a statement of the place where said article has been manufactured or produced.

Second. In the case of articles labeled, branded, or tagged, so as to plainly indicate that they are compounds, imitations, or blends, and the word "compound," "imitation," or, "blend," as the case may be, is plainly stated on the package in which it is offered for sale: *Provided,* That the term blend as used herein shall be construed to mean a mixture of like substances, not excluding harmless coloring or flavoring ingredients used for the purpose of coloring and flavoring only: *And provided further,* That nothing in this act shall be construed as requiring or compelling proprietors or manufacturers of proprietary foods which contain no unwholesome added ingedient to disclose their

[1]Page 78.

trade formulas except in so far as the provisions of this act may require to secure freedom from aduteration or misbranding.

Before stating or discussing the particular questions as to which you desire my opinion, I think it will conduce to clearness to call attention to the general purpose of this act and to some considerations founded thereon.

The primary purpose of the pure food law is to protect against fraud consumers of food or drugs; as an incidental or secondary purpose, it seeks to prevent, or, at least, discourage the use of deleterious substances for either purpose; but its first aim is to insure, so far as possible, that the purchaser of an article of food or of a drug shall obtain nothing different from what he wishes and intends to buy. According to the recognized canons of statutory construction, the language of its provisions must be interpreted with reference to and in harmony with this primary general purpose; so that, in determining the proper nomenclature for articles of food as defined in the act, the intention of the law will be best observed by giving to such articles names readily understood and conveying definite and familiar ideas to the general public, although such names may be inaccurate in the view of a chemist or physicist or an expert in some particular industrial art, as in the distillation and refining of spirits. Moreover, the same name may be given by dealers or by the general public to two or more substances varying very materially in their scientific characteristics and this fact must be given due weight in passing upon questions of branding or labeling under the law.

Human experience has associated certain impressions on the senses of taste and smell with the consumption of certain articles of food, and the so-called "flavor" which expresses the resultant of these impressions constitutes a factor of decisive weight in determining the similarity or identity of substances of this character to the mind of the ordinary member of the community, quite irrespective of the relative importance of these chemical or physical properties in the substances which impart this flavor as compared to their other chemical or physical properties. This fact is aptly illustrated by a question considered at much length in the papers referred and also submitted tome as above, namely: "What is Whisky?" A chemist or a distiller might answer this question altogether differently from the ordinary purchaser of whisky for his own consumption; but the purchaser's view of the matter is material to attain the primary purpose of the pure food law; and I think it may be safely said that what he means by "whisky" when buying it is a distilled spirit, fit for use as a beverage and having the particular flavor which human experience has classified as that of "Whisky." Undoubtedly the flavors of different kinds of spirits all known as "Whisky" differ considerably, and it may be that the general impression of their similarity is due, in some measure, to imagination or imperfect memory; nevertheless, a distinct and definite idea is suggested to the mind by the words "whisky flavor;" this idea is an essential factor in ascertaining the identity of

a spirit claimed to be whisky, and, in my opinion, it is the decisive factor in determining the relative weight of the claims of two or more kinds of spirit to the name.

With this preliminary explanation, I proceed to state what I understand to be the questions as to which my opinion is desired. In substance, there are:

First. Under what circumstances should a distilled spirit be labeled or branded "Whisky" without any qualifying words?

Second. Under what circumstances should a liquid be marked a "Blend of whiskies," or "Blended whisky," or "Blended whiskies?"

Third. Under what circumstances should a liquid be marked as a "Compound of whisky," or "Compounded whisky," and what word or words, if any, must be added to such title to make the same appropriate under the law?

Fourth. Under what circumstances, if at all, could a distilled spirit, with additions of coloring and flavoring substances, be termed "Imitation whisky?"

Before dealing directly with these questions, I think it may be well to indicate the application of this law to a class of liquids affording a field for its interpretation with less opportunity for dispute—I refer to wines. It will not be questioned that to be branded or labeled "Sherry," "Port" or "Madeira," a wine must have inherently, and not because any other substance is added to it, the flavor known as that of sherry, port or madeira, as the case may be. There are different kinds of each of these wines; experts can recognize different brands or vintages by their respective flavors, and these flavors vary considerably; nevertheless, there can be no doubt that the sherry, the port and the madeira flavors are distinct from each other, and that each of them has some quality of its own shared by all varieties of the same species of wine.

There is, however, an evident distinction to be drawn between a wine such as sherry, port or madeira, and a wine such as champagne. In the view of a chemist or physicist, champagne would be doubtless described as "a compound," for it consists essentially of a wine, of sugar and of an aerating gas, three substances obviously "unlike." The law, however, in my opinion, does not contemplate that an article should be marked as a "blend," "compound," or "imitation" unless its designation would be otherwise "false or misleading" to the consumer; and the name "Champagne" would indicate to any would-be purchaser, who was ordinarily intelligent and well-informed, a wine artificially sweetened and aerated, or, in other words, a composite substance.

To determine the proper use of the term "Blend" we must first note that the definition of the word in the law is novel and arbitrary. It is thus defined by Webster:

> Blend, n. A thorough mixture of one thing with another, as colors, liquors, etc.; a shading or merging of one color, tint, etc., into another, so that it can not be known where one ends or the other begins."

There is nothing in this definition about "likeness" in the substances mingled; this feature is introduced for some special purpose in the law, and the latter must be interpreted so as to give effect to this purpose. To show this more clearly we may also note the same Dictionary's definition of "Compound." This is:

"Compound, n. That which is compounded or formed by the union or mixture of elements, ingredients, or parts; a combination of simples."

"Compound" and "Blend" are substantially synonymous when applied to mixtures of liquids in ordinary speech, but the Pure-Food Law establishes a distinction of its own between them based upon the character of the ingredients entering into the mixture. In discussing therefore what degree of "likeness" between the mingled substances will justify their designation as a "Blend" it must be always and carefully remembered (1) that "Blend" is meant to be something essentially different from "Compound," and (2) that the subject under consideration is a name for an article of food to be embodied in a label or brand in harmony with the primary purpose of the law as above explained. Without going into metaphysical distinctions, or needless explanations, it is my opinion that effect will be most surely given to the evident intent of this provision of the law if it be held that "Blend," as a substantive, or "Blended," as an adjective, can be properly and legally used in brands or labels under the act of 1906 only when *a single substantive,* either in the singular or in the plural, need follow to appropriately and adequately designate the combination; thus we can speak of a "Blend of Teas," or a "Blended Tea," but not of a *"Blend* of Tea *and Coffee."* To state the same proposition in different language, I think the two articles mixed must be capable of accurate and sufficient description by a single generic term; they must be substances known by the same name, and that name must be sufficiently distinctive to afford reasonable warning to a purchaser.

If, therefore, the question be what ought to be called "Blend of sherry," or "Blended sherry," or "Blended sherries," I think that such terms could be applied with propriety only to a mixture of two or more sherries, and not to a mixture of sherry with port or with madeira. This is not because "likeness" does not exist between the three kinds of wine mentioned, nor because great similarity may not be found in their chemical composition; it is quite possible that, in the latter respect, some kinds of sherry would be found to have a greater resemblance to some kinds of port than to other kinds of sherry; just as the chemical composition of a diamond might have much greater similarity to that of coal than to that of some other gems; but the term "Blended sherry" could not be appropriate to a mixture of sherry and port; it would mislead an intending purchaser as to the fact that port entered into the combination; the latter might be named with equal propriety "Blended port." On the other hand,

if this mixture should be termed a "Blend of port and sherry," there is no distinction in generic designation, between a mixture of these two distinct wines and a mixture of two sherries or of two ports, and I think the law clearly intended there should be such a distinction. It might be, perhaps, consistent with the law to call such a mixture "Blended *wines*," but this title would be insufficiently specific; it might designate a mixture of burgundy and claret as well as one of port and sherry. In my opinion, it is the intent of the act of 1906 that the term "Blended sherry," or "Blend of sherry," or "Blend of sherries" shall designate a mixture of two or more kinds of sherry; while the titles "Compound of port and sherry" or "Compounded port and sherry" would appropriately designate a mixture of two *unlike* substances in the view of the law, namely, two distinct and different kinds of wine; "unlike" just as diamonds and coal are "unlike" substances.

It may be that by diluting neutral spirit (ethyl alcohol) with enough distilled water to reduce it to the normal alcoholic strength of sherry wine, and, by adding appropriate flavoring and coloring substances, a mixture can be produced which tastes and smells and looks like sherry, and when consumed produces substantially the same effects; this mixture, supposing it to contain no article deleterious to health, would be appropriately labeled or branded, under the law, "Imitation sherry." If it were mixed with real sherry, no one would for a moment claim that the two substances thus combined were sufficiently "like" to warrant the description of the resultant as a "Blend;" it could only be accurately labeled, under the law, as a "Compound of genuine and imitation sherries," a designation which would not probably promote its sale.

Applying the same principles to the choice of brands or labels for distilled spirits, and especially for whiskies, we are at once confronted by the question whether whiskey corresponds to a wine like sherry or to a wine like champagne; that is to say, whether it is a natural or artificial spirit; meaning by the first term, of course, not that it exists anywhere as a product of nature, but that it is the resultant of the process of distillation alone, without needing any further addition to furnish its characteristic qualities. In the first case, it would be assimilated to brandy or rum; in the second contingency, to gin, since gin is essentially a distilled spirit, frequently as nearly neutral as may readily be, flavored by an infusion of juniper berries. I learn from the papers referred to me that the Department of Agriculture has reached the conclusion that whisky, like brandy and rum and unlike gin, is a natural spirit, its peculiar taste and aroma being imparted to it in the course of distillation and arising primarily from essential oils existing in the substances from which it may be distilled; that is to say, it corresponds to a wine like sherry and not to a wine like champagne. This conclusion seems to be fully warranted by information contained in the papers before me and by such other information

as I have been able to obtain; nevertheless, as hereinafter set forth, the statement may, perhaps, need some qualification, or, rather, some explanation. It is doubtful, however, whether the definition of "Whisky" contained in the papers aforesaid, and which I understand to have received the approval of the Department of Agriculture, is quite broad enough to meet the general intent of the law of 1906. This definition I understand to be as follows:

"Whisky is a distillate, at the required alcoholic strength, from the fermented mash of malted cereals, or from malt with unmalted cereals, and contains the congeneric substances formed with ethyl alcohol which are volatile at the ordinary temperatures of distillation, and which give the character to the distillate."

In Webster's Dictionary "Whisky" is defined as:

"An intoxicating liquor distilled from grain, *potatoes, etc.*, especially in Scotland, Ireland, and the United States. In the United States, whisky is generally distilled from maize, rye, or wheat, but in Scotland and Ireland is often made from malted barley."

In Worcester's Dictionary it is defined as:

"A kind of spirit distilled from barley, wheat, rye, maize, *potatoes, etc.*"

In Chambers's Encyclopedia of 1875, it is defined as follows:

"A spirit made by distillation from grain of any sort and from other materials, as buckwheat, *potatoes and even turnips.*"

A large number of similar definitions from standard popular works of reference might be given, and I think there can be no doubt that a spirit generally known and described as "Whisky" is often distilled from potatoes and occasionally from some other substances which could scarcely be correctly classed as cereals. I note this fact because it appears to me contrary to the spirit and subversive of the purpose of the pure-food law to adopt a definition which would exclude from the name any substance generally understood by the public to be entitled to it; that is to say, the nomenclature adopted to give effect to the Act ought to be, in my opinion, popular and not scientific. This matter, however, is of only subordinate importance in connection with the questions immediately under discussion.

It being admitted that whisky is a natural spirit having certain "congeneric substances," which, in the language of the above definition "give the character to the distillate," it seems obvious that a mixture of two or more different whiskies as thus defined, whether their differences arise from the character of the substances from which they were distilled or from the method of distillation used in each case respectively, or even from their several ages and the environment in which they were kept subsequently to distillation, would be appropriately termed a "Blend of whiskies," or "Blended whisky," or "Blended whiskies;" any one of these three terms would be appropriate,

provided that each article entering into the combination, standing alone, would be appropriately designated as "Whisky."

The mixture of a spirit properly designated as "Whisky" with another spirit which, standing alone, would not be properly designated as "Whisky," such as ethyl alcohol, must, in my opinion, be labeled or branded as a "Compound," or as "Compounded." This question has given rise to a very animated dispute, and it is understood that great importance is attached by dealers to its determination, which is thought to involve serious pecuniary loss or gain to some or others among them. I have, therefore, considered it very carefully. In Chambers's Encyclopedia, above quoted, Volume III, article "Distillation," occurs the following passage:

"If only alcohol and water passed over in distillation, *all spirits, from whatever extracted, would be the same;* but this is not the case. Brandy, which is distilled from wine, has a peculiar essential oil derived from the grape and also some acid; rum is impregnated with an essential oil from the sugar cane, and with other impurities; malt liquor has the essential oil of barley, etc. It is these essential oils that give to the various spirits their distinguishing flavors. Some of the oils and other impurities are disagreeable and positively noxious, and it is one of the objects of *rectifying* to remove these. The mellowing effects of age upon spirits is owing to the evaporation, or spontaneous decomposition of the essential oils. Newly distilled spirits are, in general, fiery and specially unwholesome."

This statement from a popular work seems to be fully sustained by works of greater scientific authority and shows, in my opinion, that, for the purposes of the pure-food law, neutral spirit or ethyl alcohol, if absolutely pure, would be, not only *like,* but actually *identical,* whether it were derived from fruit, from cereals, from sugar cane, or from any other of the many substances which can furnish alcohol. Inasmuch as a state of *absolute* purity can not be attained by any treatment appropriate for commercial purposes, it may be, perhaps, more nearly accurate to say that each of these different kinds of neutral spirit is a *like* substance to one of any other kind; but, if we concede that ethyl alcohol is a "like substance" to whisky, then we must also concede that brandy and rum are "like substances" to whisky also, because each of them, on precisely the same grounds, can be likened to neutral spirit. It is undoubtedly true that only a very small proportion (less than the half of 1 *per centum*) of the ingredients entering into whisky are different from those entering into neutral spirit; but this is equally true of brandy and rum, and it is precisely those substances which "give the character to the distillate" in each of these cases.

In the nature of things there can have been, as yet, no judicial decisions as to the meaning of the terms used in the pure-food law, but section 3287 of the United States Revised Statutes, as amended in 1879, 1880 and 1890, has been cited to me to show the "likeness" of whisky and neutral spirit as matter of law; I find, however, nothing

in that section at all relevant to the present discussion. It requires the cask to indicate "the particular name of such distilled spirits as known to the trade, that is to say, *high wines, alcohol* or *spirits,* as the case may be." It is undoubtedly true that in distillation under the improved methods of modern times a neutral spirit may be produced at a later stage of the process out of something which at an earlier stage of the process was crude whisky or so-called "high wines;" but this no more shows neutral spirit to be a "like substance" to whisky than vinegar is a "like substance" to cider or to wine, or that beef is a "like substance" to veal.

My attention has been likewise called to the case of *Taylor Company vs. Taylor* in the Court of Appeals of Kentucky (85 S. W. R., 1085) as establishing the propriety of designating a mixture of whisky and ethyl alcohol as "a blend" or "blended." In this case it was determined that the selling of whisky mixed with neutral spirit under a label which might lead the uninitiated to suppose that it was a "straight whisky" was a fraud upon the public as well as upon the manufacturer of the "straight" article. In its opinion the court says:

"The defendant may properly sell his brand of 'Old Kentucky Taylor,' provided he so frames his advertisements as to show that it is a blended whiskey; but he can not be allowed to impose upon the public a cheaper article and thus deprive appellant of the fruits of his energy and expenditures by selling his blended whiskey under labels or advertisements which conceal the true character of the article, for this would destroy the value of the appellant's trade."

This decision was rendered on March 17, 1905, more than a year before the approval of the pure-food law; in speaking of a mixture of whisky and neutral spirit as "blended whisky," the court had not, of course, in mind the definition of "Blend" in that law, which, as above noted, is altogether novel and arbitrary; on the other hand, the decision may have been considered by the Congress when it framed the pure-food law; and the special and original definition of "Blend" given in that law, may have been intended for the very purpose of making more difficult such frauds as the Court of Appeals in Kentucky condemned in this case.

I conclude, therefore, that according to the true intent of the pure-food law, a mixture of whisky with neutral spirit must be deemed a "Compound" and not a "Blend," although the spirit may be a distillate from the same substance used to furnish the whisky, and that such a mixture stands on the same footing as a mixture of whisky and brandy or of whisky and rum.

The definition of "Whisky" as a natural spirit involves as its corollary that there *can* be such a thing as "Imitation whisky." If the same process were followed of which we spoke in connection with artificial wine, namely, if ethyl alcohol, either pure or mixed with distilled water, were given, by the addition of harmless coloring and flavoring substances, the appearance and flavor of whisky, it is impos-

sible to find any other name for the product, in conformity with the pure-food law, than "Imitation whisky."

An interesting question remains, the question, in any opinion, of greatest difficulty connected with the subject; namely, whether a mixture of a liquid such as has just been described, or, indeed, a mixture of ethyl alcohol itself with whisky ought to be labeled "Whisky" at all. When the words "Compound" or "Compounded" are used in the act, it is, in my judgment, *ordinarily* necessary, that *two* substances, at least, should be mentioned as entering into the combination described; in other words, it would not be accurate to call a mixture of port and sherry "Compounded sherry" or "Compounded port;" such a mixture must be designated as "Sherry compounded with port" or "Port compounded with sherry" or "Compound of port and sherry." As above stated, this would be, to say the least, no less true if an imitation sherry were used to mix with a genuine sherry, and, at first sight, it would seem that the same reasoning would deny the name "Whisky" to a compound of "straight" whisky and ethyl alcohol whether with or without coloring and flavoring substances. There is, however, a distinction between the two cases, and it is not *universally* true that *two* substantives *must* follow "Compound" or "Compounded," although it is true, in my opinion, that only one substantive can appropriately follow "Blend" or "Blended."

In the first place, we may note that the "Imitation sherry" described above would not be a wine at all, while ethyl alcohol is clearly a spirit; this distinction, however, is not essential. But, so far as I know, no practice exists in the wine trade of mixing port with sherry or genuine with artificial sherry and calling the mixture by the name of either one of its ingredients. On the other hand, there is and has been for a long time in existence a well-known practice of mixing ethyl alcohol with whisky to give the latter an artificial age and thus produce the so-called "mellowness" of old whisky, which is caused by the gradual and partial evaporation of the essential oils contained in new whisky; and it seems to be a long and well established custom in the trade to call the mixture of whisky and alcohol thus produced "Blended whisky." For the reasons above set forth, I think the law has forbidden the use of the adjective, but it is otherwise with the noun.

In the Encyclopædia Britannica of 1878, Vol. VII, under the head "Distillation," there is the following statement:

"Flat bottomed and fire heated stills are considered the best for the distillation of malt spirit, as by them the flavor is preserved. Coffey's still, on the other hand, is the best for the distillation of grain spirit, as by it a spirit is obtained almost entirely destitute of flavor and of a strength varying from 55 to 70 over proof. Spirit produced of this high strength evaporates at such a low temperature that scarcely any of the volatile oils on which the peculiar flavor of spirits depends are evaporated with it, hence the reason why it is not adapted for the distillation of malt whiskey which requires a certain amount of

these oils to give it its requisite flavor. The spirit produced by Coffey's still is, therefore, chiefly used for making gin and factitious brandy by the rectifiers, *or for being mixed with malt whiskies by the wholesale dealers.*"

The practice therein described has become during the past twenty-eight years much more general than it then was, in the United States as well as in Great Britain, and improvements in the art of distillation have rendered it much easier and more profitable.

As above explained, I consider "Champagne" a suitable label or brand for the composite wine known by that name. If a natural wine existed which was sweet and sparkling and also generally known as "Champagne," a mixture of the two might be, I think, appropriately called "Compound" or "Compounded champagne," and, in accordance with this analogy, I conclude that a combination of whisky with ethyl alcohol, supposing, of course, that there is enough whisky in it to make it a *real* compound and not the mere semblance of one, may be fairly called, "Whisky;" provided the name is accompanied by the word "Compound" or "Compounded," and provided a statement of the presence of another spirit is included in substance in the title. I am strengthened in this conclusion by understanding from the papers you have referred to me that it has been reached by the Department of Agriculture as well.

The following seem to me appropriate specimen brands or labels for (1) "straight" whisky, (2) a mixture of two or more "straight" whiskies, (3) a mixture of "straight" whisky and ethyl alcohol, and (4) ethyl alcohol flavored and colored so as to taste, smell, and look like whisky:

(1) Semper Idem Whisky: A pure, straight whisky mellowed by age.

(2) E Pluribus Unum Whisky: A blend of pure, straight whiskies with all the merits of each.

(3) Modern Improved Whisky: A compound of pure grain distillates, mellow and free from harmful impurities.

(4) Something Better than Whisky: An imitation under the pure-food law, free from fusel oil and other impurities.

In the third specimen it is assumed that *both* the whisky and the alcohol are distilled from grain.

I remain, sir, yours very respectfully and truly,

CHARLES J. BONAPARTE,
Attorney-General.

UNITED STATES DEPARTMENT OF AGRICULTURE,

OFFICE OF THE SECRETARY.—Circular No. 19.

STANDARDS OF PURITY FOR FOOD PRODUCTS.

Superseding Circulars Nos. 13 and 17.

Supplemental Proclamation.

Referring to Circular No. 13 of this Office, dated December 20, 1904, and to Circular No. 17 of this Office, dated March 8, 1906, the following food standards are hereby established as superseding and supplemental to those proclaimed on the dates above named.

JAMES WILSON,
Secretary of Agriculture.

WASHINGTON, D. C., *June 26, 1906.*

LETTER OF SUBMITTAL.

The Honorable the SECRETARY OF AGRICULTURE.

Sir: The undersigned, representing the Association of Official Agricultural Chemists of the United States and the Interstate Food Commission, and commissioned by you, under authority given by the act of Congress approved March 3, 1903, to collaborate with you "to establish standards of purity for food products and to determine what are regarded as adulterations therein," respectfully report that they have carefully reviewed, in the light of recent investigations and correspondence, the standards earlier recommended by them and have prepared a set of amended schedules, in which certain changes have been introduced for the purpose of securing increased accuracy of expression and a more perfect correspondence of the chemical limits to the normal materials designated, and from which standards previously proclaimed for several manufactured articles have been omitted because of the unsatisfactory condition of trade nomenclature as applied thereto; and also additional schedules of standards for ice creams, vegetables and vegetable products, tea and coffee. They respectfully recommend that the standards herewith submitted be

approved and proclaimed as the established standards, superseding and supplementing those established on December 20, 1904, and March 8, 1906.

The principles that have guided us in the formulation of these standards are appended hereto.

The several schedules of additional standards recommended have been submitted, in a tentative form, to the manufacturing firms and the trade immediately interested, and also to the State food-control officials for criticism.

Respectfully,

WILLIAM FREAR,
EDWARD H. JENKINS,
M. A. SCOVELL,
H. A. WEBER,
H. W. WILEY,
Committee on Food Standards,
Association of Official Agricultural Chemists.
RICHARD FISCHER,
Representing the Interstate Food Commission.

WASHINGTON, D. C., *June 26, 1906.*

PRINCIPLES ON WHICH THE STANDARDS ARE BASED.

The general considerations which have guided the committee in preparing the standards for food products are the following:

1. The standards are expressed in the form of definitions, with or without accompanying specifications of limit in composition.
2. The main classes of food articles are defined before the subordinate classes are considered.
3. The definitions are so framed as to exclude from the articles defined substances not included in the definitions.
4. The definitions include, where possible, those qualities which make the articles described wholesome for human food.
5. A term defined in any of the several schedules has the same meaning wherever else it is used in this report.
6. The names of food products herein defined usually agree with existing American trade or manufacturing usage; but where such usage is not clearly established or where trade names confuse two or more articles for which specific designations are desirable, preference is given to one of the several trade names applied.
7. Standards are based upon data representing materials produced under American conditions and manufactured by American processes or representing such varieties of foreign articles as are chiefly imported for American use.
8. The standards fixed are such that a departure of the articles to which they apply, above the maximum or below the minimum limit prescribed, is evidence that such articles are of inferior or abnormal quality.
9. The limits fixed as standard are not necessarily the extremes authentically recorded for the article in question, because such extremes are commonly due to abnormal conditions of production and are usually accompanied by marks of inferiority or abnormality readily perceived by the producer or manufacturer.

FOOD STANDARDS.

I. ANIMAL PRODUCTS.

A. Meats and the Principal Meat Products.

a. MEATS.

1. *Meat, flesh,* is any clean, sound, dressed, and properly prepared edible part of animals in good health at the time of slaughter, and if it bears a name descriptive of its kind, composition, or origin, it corresponds thereto. The term "animals," as herein used, includes not only mammals, but fish, fowl, crustaceans, mollusks, and all other animals used as food.

2. *Fresh meat* is meat from animals recently slaughtered and properly cooled until delivered to the consumer.

3. *Cold storage meat* is meat from animals recently slaughtered and preserved by refrigeration until delivered to the consumer.

4. *Salted, pickled,* and *smoked meats* are unmixed meats preserved by salt, sugar, vinegar, spices, or smoke, singly or in combination, whether in bulk or in suitable containers.

b. MANUFACTURED MEATS.

1. *Manufactured meats* are meats not included in paragraphs 2, 3, and 4, whether simple or mixed, whole or comminuted, in bulk or in suitable containers, with or without the addition of salt, sugar, vinegar, spices, smoke, oils, or rendered fat. If they bear names descriptive of kind, composition, or origin, they correspond thereto and when bearing such descriptive names, if force or flavoring meats are used, the kind and quantity thereof are made known.

c. MEAT EXTRACTS, MEAT PEPTONES, ETC.

(Schedule in preparation.)

d. LARD.

1. *Lard* is the rendered fresh fat from hogs in good health at the time of slaughter, is clean, free from rancidity, and contains, necessarily incorporated in the process of rendering, not more than one (1) per cent of substances, other than faty acids and fat.

2. *Leaf lard* is lard rendered at moderately high temperatures from the internal fat of the abdomen of the hog, excluding that adherent to the intestines, and has an iodin number not greater than sixty (60).

3. *Neutral lard* is lard rendered at low temperatures.

B. Milk and Its Products.

a. MILKS.

1. *Milk* is the fresh, clean, lacteal secretion obtained by the complete milking of one or more healthy cows, properly fed and kept, excluding that obtained within fifteen days before and ten days after calving, and contains not less than eight and one-half (8.5) per cent of soilds not fat, and not less than three and one-quarter (3.25) per cent of milk fat.

2. *Blended milk* is milk modified in its composition so as to have a definite and stated percentage of one or more of its constituents.

3. *Skim milk* is milk from which a part or all of the cream has been

removed and contains not less than nine and one-quarter (9.25) per cent of milk solids.

4. *Pasteurized milk* is milk that has been heated below boiling but sufficiently to kill most of the active organisms present and immediately cooled to 50° Fahr. or lower.

5. *Sterilized milk* is milk that has been heated at the temperature of boiling water or higher for a length of time sufficient to kill all organisms present.

6. *Condensed milk, evaporated milk,* is milk from which a considerable portion of water has been evaporated and contains not less than twenty-eight (28) per cent of milk solids of which not less than twenty-seven and five-tenths (27.5) per cent is milk fat.

7. *Sweetened condensed milk* is milk from which a considerable portion of water has been evaporated and to which sugar (sucrose) has been added, and contains not less than twenty-eight (28) per cent of milk solids, of which not less than twenty-seven and five-tenths (27.5) per cent is milk fat.

8. *Condensed skim milk* is skim milk from which a considerable portion of water has been evaporated.

9. *Buttermilk* is the product that remains when butter is removed from milk or cream in the process of churning.

10. *Goat's milk, ewe's milk, et cetera,* are the fresh, clean lacteal secretions, free from colostrum, obtained by the complete milking of healthy animals other than cows, properly fed and kept, and conform in name to the species of animal from which they are obtained.

b. CREAM.

1. *Cream* is that portion of milk, rich in milk fat, which rises to the surface of milk on standing, or is separated from it by centrifugal force, is fresh and clean and contains not less than eighteen (18) per cent of milk fat.

2. *Evaporated cream, clotted cream,* is cream from which a considerable portion of water has been evaporated.

c. MILK FAT OR BUTTER FAT.

1. *Milk fat, butter fat,* is the fat of milk and has a Reichert-Meissl number not less than twenty-four (24) and a specific gravity not less than 0.905 $\left(\frac{40^\circ \text{ C.}}{40^\circ \text{ C.}}\right)$

d. BUTTER.

1. *Butter* is the clean, non-rancid product made by gathering in any manner the fat of fresh or ripened milk or cream into a mass, which also contains a small portion of the other milk constituents, with or without salt, and contains not less than eighty-two and five-tenths (82.5) per cent of milk fat. By acts of Congress approved August 2, 1886, and May 9, 1902, butter may also contain added coloring matter.

2. *Renovated butter, process butter,* is the product made by melting butter and reworking, without the addition or use of chemicals or any substances except milk, cream, or salt, and contains not more than sixteen (16) per cent of water and at least eighty-two and five-tenths (82.5) per cent of milk fat.

e. CHEESE.

1. *Cheese* is the sound, solid, and ripened product made from milk or cream by coagulating the casein thereof with rennet or lactic acid,

with or without the addition of ripening ferments and seasoning, and contains, in the water-free substance, not less than fifty (50) per cent of milk fat. By act of Congress, approved June 6, 1896, cheese may also contain added coloring matter.

2. *Skim milk cheese* is the sound, solid, and ripened product, made from skim milk by coagulating the casein thereof with rennet or lactic acid, with or without the addition of ripening ferments and seasoning.

3. *Goat's milk cheese, ewe's milk cheese, et cetera,* are the sound, ripened products made from the milks of the animals specified, by coagulating the casein thereof with rennet or lactic acid, with or without the addition of ripening ferments and seasoning.

f. ICE CREAM.

1. *Ice cream* is a frozen product made from cream and sugar, with or without a natural flavoring, and contains not less than fourteen (14) per cent of milk fat.

2. *Fruit ice cream* is a frozen product made from cream, sugar, and sound, clean, mature fruits, and contains not less than twelve (12) per cent of milk fat.

3. *Nut ice cream* is a frozen product made from cream, sugar, and sound, non-rancid nuts, and contains not less than twelve (12) per cent of milk fat.

g. MISCELLANEOUS MILK PRODUCTS.

1. *Whey* is the product remaining after the removal of fat and casein from milk in the process of cheese-making.

2. *Kumiss* is the product made by the alcoholic fermentation of mare's or cow's milk.

II. VEGETABLE PRODUCTS.

A. GRAIN PRODUCTS.

a. GRAINS AND MEALS.

1. *Grain* is the fully matured, clean, sound, air-dry seed of wheat, maize, rice, oats, rye, buckwheat, barley, sorghum, millet, or spelt.

2. *Meal* is the clean, sound product made by grinding grain.

3. *Flour* is the fine, clean, sound product made by bolting wheat meal and contains not more than thirteen and one-half (13.5) per cent of moisture, not less than one and twenty-five hundredths (1.25) per cent of nitrogen, not more than one (1) per cent of ash, and not more than fifty hundredths (0.50) per cent of fiber.

4. *Graham flour* is unbolted wheat meal.

5. *Gluten flour* is the clean, sound product made from flour by the removal of starch and contains not less than five and six-tenths (5.6) per cent of nitrogen and not more than ten (10) per cent of moisture.

6. *Maize meal, corn meal, Indian corn meal,* is meal made from sound maize grain and contains not more than fourteen (14) per cent of moisture, not less than one and twelve hundredths (1.12) per cent of nitrogen, and not more than one and six-tenths (1.6) per cent of ash.

7. *Rice* is the hulled, or hulled and polished grain of *Oryza sativa.*

8. *Oatmeal* is meal made from hulled oats and contains not more than twelve (12) per cent of moisture, not more than one and five-tenths (1.5) per cent of crude fiber, not less than two and twenty-four hundredths (2.24) per cent of nitrogen, and not more than two and two-tenths (2.2) per cent of ash.

9. *Rye flour* is the fine, clean, sound product made by bolting rye meal and contains not more than thirteen and one-half (13.5) per cent of moisture, not less than one and thirty-six hundredths (1.36) per cent of nitrogen, and not more than one and twenty-five hundredths (1.25) per cent of ash.

10. *Buckwheat flour* is bolted buckwheat meal and contains not more than twelve (12) per cent of moisture, not less than one and twenty-eight hundredths (1.28) per cent of nitrogen, and not more than one and seventy-five hundredths (1.75) per cent of ash.

B. Fruit and Vegetables.

a. Fruit and Fruit Products.

(Except fruit juices, fresh, sweet, and fermented, and vinegars.)

1. *Fruits* are the clean, sound, edible, fleshy fructifications of plants, distinguished by their sweet, acid, and ethereal flavors.

2. *Dried fruit* is the clean, sound product made by drying mature, properly prepared, fresh fruit in such a way as to take up no harmful substance, and conforms in name to the fruit used in its preparation; *sun-dried fruit* is dried fruit made by drying without the use of artificial means; *evaporated fruit* is dried fruit made by drying with the use of artificial means.

3. *Evaporated apples* are evaporated fruit made from peeled and cored apples, and contain not more than twenty-seven (27) per cent of moisture determined by the usual commercial method of drying for four (4) hours at the temperature of boiling water.

(Standards for other dried fruits are in preparation.)

4. *Canned fruit* is the sound product made by sterilizing clean, sound, properly matured and prepared fresh fruit, by heating, with or without sugar (sucrose) and spices, and keeping in suitable, clean, hermetically sealed containers and conforms in name to the fruit used in its preparation.

5. *Preserve* is the sound product made from clean, sound, properly matured and prepared fresh fruit and sugar (sucrose) sirup, with or without spices or vinegar, and conforms in name to that of the fruit used, and in its preparation not less than forty-five (45) pounds of fruit are used to each fifty-five (55) pounds of sugar.

6. *Honey preserve* is preserve in which honey is used in place of sugar (sucrose) sirup.

7. *Glucose preserve* is preserve in which a glucose product is used in place of sugar (sucrose) sirup.

8. *Jam, marmalade;* is the sound product made from clean, sound, properly matured and prepared fresh fruit and sugar (sucrose), with or without spices or vinegar, by boiling to a pulpy or semisolid consistence, and conforms in name to the fruit used, and in its preparation not less than forty-five (45) pounds of fruit are used to each fifty-five (55) pounds of sugar.

9. *Glucose jam, glucose marmalade* is jam in which a glucose product is used in place of sugar (sucrose).

10. *Fruit butter* is the sound product made from fruit juice and clean, sound, properly matured and prepared fruit, evaporated to a semisolid mass of homogeneous consistence, with or without the addition of sugar and spices or vinegar, and conforms in name to the fruit used in its preparation.

11. *Glucose fruit butter* is fruit butter in which a glucose product is used in place of sugar (sucrose).

12. *Jelly* is the sound, semisolid, gelatinous product made by boil-

ing clean, sound, properly matured and prepared fresh fruit with water, concentrating the expressed and strained juice, to which sugar (sucrose) is added, and conforms in name to the fruit used in its preparation.

13. *Glucose jelly* is jelly in which a glucose product is used in place of sugar (sucrose).

b. VEGETABLES AND VEGETABLE PRODUCTS.

1. *Vegetables* are the succulent, clean, sound, edible parts of herbaceous plants used for culinary purposes.

2. *Dried vegetables* are the clean, sound products made by drying properly matured and prepared vegetables in such a way as to take up no harmful substance, and conform in name to the vegetables used in their preparation; *sun-dried vegetables* are dried vegetables made by drying without the use of artificial means; *evaporated vegetables* are dried vegetables made by drying with the use of artificial means.

3. *Canned vegetables* are sound, properly matured and prepared fresh vegetables, with or without salt, sterilized by heat, with or without previous cooking in vessels from which they take up no metallic substance, kept in suitable, clean, hermetically sealed containers, are sound and conform in name to the vegetables used in their preparation.

4. *Pickles* are clean, sound, immature cucumbers, properly prepared, without taking up any metallic compound other than salt, and preserved in any kind of vinegar, with or without spices; *pickled onions, pickled beets, pickled beans*, and other pickled vegetables are vegetables prepared as described above, and conform in name to the vegetables used.

5. *Salt pickles* are clean, sound, immature cucumbers, preserved in a solution of common salt, with or without spices.

6. *Sweet pickles* are pickled cucumbers or other vegetables in the preparation of which sugar (sucrose) is used.

7. *Sauerkraut* is clean, sound, properly prepared cabbage, mixed with salt, and subjected to fermentation.

8. *Catchup* (*ketchup, catsup*) is the clean, sound product made from the properly prepared pulp of clean, sound, fresh, ripe tomatoes, with spices and with or without sugar and vinegar; *mushroom catchup, walnut catchup, et cetera*, are catchups made as above described, and conform in name to the substances used in their preparation.

C. SUGARS AND RELATED SUBSTANCES.

a. SUGAR AND SUGAR PRODUCTS.

SUGARS.

1. *Sugar* is the product chemically known as sucrose (saccharose) chiefly obtained from sugar cane, sugar beets, sorghum, maple, and palm.

2. *Granulated, loaf, cut, milled*, and *powdered sugars* are different forms of sugar and contain at least ninety-nine and five-tenth (99.5) per cent of sucrose.

3. *Maple sugar* is the solid product resulting from the evaporation of maple sap, and contains, in the water-free substance, not less than sixty-five one-hundredths (0.65) per cent of maple sugar ash.

4. *Massecuite, melada, mush sugar*, and *concrete* are products made by evaporating the purified juice of a sugar-producing plant, or a solution of sugar, to a solid or semisolid consistence, and in which the sugar chiefly exists in a crystalline state.

MOLASSES AND REFINERS' SIRUP.

1. *Molasses* is the product left after separating the sugar from massecuite, melada, mush sugar, or concrete, and contains not more than

twenty-five (25) per cent of water and not more than five (5) per cent of ash.

2. Refiners' sirup, treacle, is the residual liquid product obtained in the process of refining raw sugars and contains not more than twenty-five (25) per cent of water and not more than eight (8) per cent of ash.

SIRUPS.

1. *Sirup* is the sound product made by purifying and evaporating the juice of a sugar-producing plant without removing any of the sugar.

2. *Sugar-cane sirup* is sirup made by the evaporation of the juice of the sugar-cane or by the solution of sugar-cane concrete, and contains not more than thirty (30) per cent of water and not more than two and five-tenths (2.5) per cent of ash.

3. *Sorghum sirup* is sirup made by the evaporation of sorghum juice or by the solution of sorghum concrete, and contains not more than thirty (30) per cent of water and not more than two and five-tenths (2.5) per cent of ash.

4. *Maple sirup* is sirup made by the evaporation of maple sap or by the solution of maple concrete, and contains not more than thirty-two (32) per cent of water and not less than forty-five hundredths (0.45) per cent of maple sirup ash.

5. *Sugar sirup* is the product made by dissolving sugar to the consistence of a sirup and contains not more than thirty-five (35) per cent of water.

b. GLUCOSE PRODUCTS.

1. *Starch sugar* is the solid product made by hydrolyzing starch or a starch-containing substance until the greater part of the starch is converted into dextrose. Starch sugar appears in commerce in two forms, anhydrous starch sugar and hydrous starch sugar. The former, crystallized without water of crystallization, contains not less than ninety-five (95) per cent of dextrose and not more than eight-tenths (0.8) per cent of ash. The latter, crystallized with water of crystallization, is of two varieties—70 sugar, also known as brewers' sugar, contains not less than seventy (70) per cent of dextrose and not more than eight-tenths (0.8) per cent of ash; 80 sugar, climax or acme sugar, contains not less than eighty (80) per cent of dextrose and not more than one and one-half (1.5) per cent of ash.

The ash of all these products consists almost entirely of chlorids and sulphates.

2. *Glucose, mixing glucose, confectioner's glucose,* is a thick, sirupy, colorless product made by incompletely hydrolyzing starch, or a starch-containing substance, and decolorizing and evaporating the product. It varies in density from forty-one (41) to forty-five (45) degrees Baumé at a temperature of 100° Fahr. (37.7° C.), and conforms in density, within these limits, to the degree Baumé it is claimed to show, and for a density of forty-one (41) degrees Baumé contains not more than twenty-one (21) per cent and for a density of forty-five (45) degrees not more than fourteen (14) per cent of water. It contains on a basis of forty-one (41) degrees Baumé not more than one (1) per cent of ash, consisting chiefly of chlorids and sulphates.

c. CANDY.

1. *Candy* is a product made from a saccharine substance or substances with or without the addition of harmless coloring, flavoring, or

filling materials and contains no terra alba, barytes, talc, chrome yellow, or other mineral substances, or poisonous colors or flavors, or other ingredients deleterious or detrimental to health, or any vinous, malt, or spirituous liquor or compound, or narcotic drug.

d. HONEY.

1. *Honey* is the nectar and saccharine exudations of plants gathered, modified, and stored in the comb by honey bees (*Apis mellifica* and *A. dorsata*); is lævo-rotatory, contains not more than twenty-five (25) per cent of water, not more than twenty-five hundredths (0.25) per cent of ash, and not more than eight (8) per cent of sucrose.
2. *Comb honey* is honey contained in the cells of comb.
3. *Extracted honey* is honey which has been separated from the uncrushed comb by centrifugal force or gravity.
4. *Strained honey* is honey removed from the crushed comb by straining or other means.

D. CONDIMENTS (EXCEPT VINEGAR AND SALT).

a. SPICES.

1. *Spices* are aromatic vegetable substances used for the seasoning of food and from which no portion of any volatile oil or other flavoring principle has been removed and which are clean, sound, and true to name.
2. *Allspice, pimento,* is the dried fruit of the *Pimenta pimenta* (L.) Karst., and contains not less than eight (8) per cent of quercitannic acid;[a] not more than six (6) per cent of total ash, not more than five-tenths (0.5) per cent of ash insoluble in hydrochloric acid, and not more than twenty-five (25) per cent of crude fiber.
3. *Anise* is the fruit of the *Pimpinella anisum* L.
4. *Bay leaf* is the dried leaf of *Laurus nobilis* L.
5. *Capers* are the flower buds of *Capparis spinosa* L.
6. *Caraway* is the fruit of *Carum carvi* L.

CAYENNE AND RED PEPPERS.

7. *Red pepper* is the red, dried, ripe fruit of any species of *Capsicum.*
8. *Cayenne pepper, cayenne,* is the dried ripe fruit of *Capsicum frutescens* L., *Capsicum baccatum* L., or some other small-fruited species of *Capsicum,* and contains not less than fifteen (15) per cent of non-volatile ether extract; not more than six and five-tenths (6.5) per cent of total ash; not more than five-tenths (0.5) per cent of ash insoluble in hydrochloric acid; not more than one and five-tenths (1.5) per cent of starch, and not more than twenty-eight (28) per cent of crude fiber.
9. *Paprika* is the dried ripe fruit of *Capsicum annuum* L., or some other large-fruited species of *Capsicum,* excluding seeds and stems.
10. *Celery seed* is the dried fruit of *Apium graveolens* L.
11. *Cinnamon* is the dried bark of any species of the genus *Cinnamomum* from which the outer layers may or may not have been removed.
12. *True cinnamon* is the dried inner bark of *Cinnamomum zeylanicum* Breyne.
13. *Cassia* is the dried bark of various species of *Cinnamomum,* other than *Cinnamomum zeylanicum,* from which the outer layers may or may not have been removed.

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[a] Calculated from the total oxygen absorbed by the aqueous extract.

14. *Cassia buds* are the dried immature fruit of species of *Cinnamomum.*

15. *Ground cinnamon, ground cassia,* is a powder consisting of cinnamon, cassia, or cassia buds, or a mixture of these spices, and contains not more than six (6) per cent of total ash and not more than two (2) per cent of sand.

16. *Cloves* are the dried flower buds of *Caryophyllus aromaticus* L., which contain not more than five (5) per cent of clove stems; not less than ten (10) per cent of volatile ether extract; not less than twelve (12) per cent of quercitannic acid[a]; not more than eight (8) per cent of total ash; not more than five-tenths (0.5) per cent of ash insoluble in hydrochloric acid, and not more than ten (10) per cent of crude fiber.

17. *Coriander* is the dried fruit of *Coriandrum sativum* L.

18. *Cumin seed* is the fruit of *Cuminum cyminum* L.

19. *Dill seed* is the fruit of *Anethum graveolens* L.

20. *Fennel* is the fruit of *Foeniculum foeniculum* (L.) Karst.

21. *Ginger* is the washed and dried or decorticated and dried rhizome of *Zinziber zingiber* (L.) Karst., and contains not less than forty-two (42) per cent of starch; not more than eight (8) per cent of crude fiber, not more than six (6) per cent of total ash, not more than one (1) per cent of lime, and not more than three (3) per cent of ash insoluble in hydrochloric acid.

22. *Limed ginger, bleached ginger,* is whole ginger coated with carbonate of lime and contains not more than ten (10) per cent of ash, not more than four (4) per cent of carbonate of lime, and conforms in other respects to the standard for ginger.

23. *Horse-radish* is the root of *Roripa armoracia* (L.) Hitchcock, either by itself or ground and mixed with vinegar.

24. *Mace* is the dried arillus of *Myristica fragrans* Houttuyn, and contains not less than twenty (20) nor more than thirty (30) per cent of nonvolatile ether extract, not more than three (3) per cent of total ash, and not more than five-tenths (0.5) per cent of ash insoluble in hydrochloric acid, and not more than ten (10) per cent of crude fiber.

25. *Macassar mace, Papua mace,* is the dried arillus of *Myristica argentea* Warb.

26. *Bombay mace* is the dried arillus of *Myristica malabarica* Lamarck.

27. *Marjoram* is the leaf, flower and branch of *Majorana majorana* (L.) Karst.

28. *Mustard seed* is the seed of *Sinapis alba* L. (white mustard), *Brassica nigra* (L.) Koch (black mustard), or *Brassica juncea* (L.) Cosson (black or brown mustard).

29. *Ground mustard* is a powder made from mustard seed, with or without the removal of the hulls and a portion of the fixed oil, and contains not more than two and five-tenths (2.5) per cent of starch and not more than eight (8) per cent of total ash.

30. *Prepared mustard, German mustard, French mustard, mustard paste,* is a paste composed of a mixture of ground mustard seed or mustard flour with salt, spices and vinegar, and, calculated free from water, fat and salt, contains not more than twenty-four (24) per cent of carbohydrates, calculated as starch, determined according to the official methods, not more than twelve (12) per cent of crude fiber nor less than thirty-five (35) per cent of protein, derived solely from the materials named.

31. *Nutmeg* is the dried seed of the *Myristica fragrans* Houttuyn, deprived of its testa, with or without a thin coating of lime, and con-

a Calculated from the total oxygen absorbed by the aqueous extract.

tains not less than twenty-five (25) per cent of nonvolatile ether extract, not more than five (5) per cent of total ash, not more than five-tenths (0.5) per cent of ash insoluble in hydrochloric acid, and not more than ten (10) per cent of crude fiber.

32. *Macassar nutmeg, Papua nutmeg, male nutmeg, long nutmeg,* is the dried seed of *Myristica argentea* Warb. deprived of its testa.

PEPPER.

33. *Black pepper* is the dried immature berry of *Piper nigrum* L. and contains not less than six (6) per cent of nonvolatile ether extract, not less than twenty-five (25) per cent of starch, not more than seven (7) per cent of total ash, not more than two (2) per cent of ash insoluble in hydrochloric acid, and not more than fifteen (15) per cent of crude fiber. One hundred parts of the nonvolatile ether extract contain not less than three and one-quarter (3.25) parts of nitrogen. *Ground black pepper* is the product made by grinding the entire berry and contains the several parts of the berry in their normal proportions.

34. *Long pepper* is the dried fruit of *Piper longum* L.

35. *White pepper* is the dried mature berry of *Piper nigrum* L. from which the outer coating or the outer and inner coatings have been removed and contains not less than six (6) per cent of nonvolatile ether extract, not less than fifty (50) per cent of starch, not more than four (4) per cent of total ash, not more than five-tenths (0.5) per cent of ash insoluble in hydrochloric acid, and not more than five (5) per cent of crude fiber. One hundred parts of the nonvolatile ether extract contain not less than four (4) parts of nitrogen.

36. *Saffron* is the dried stigma of *Crocus sativus* L.

37. *Sage* is the leaf of *Salvia officinalis* L.

38. *Savory, summer savory,* is the leaf, blossom, and branch of *Satureja hortensis* L.

39. *Thyme* is the leaf and tip of blooming branches of *Thymus vulgaris* L.

b. FLAVORING EXTRACTS.

1. *A flavoring extract*[a] is a solution in ethyl alcohol of proper strength of the sapid and odorous principles derived from an aromatic plant, or parts of the plant, with or without its coloring matter, and conforms in name to the plant used in its preparation.

2. *Almond extract* is the flavoring extract prepared from oil of bitter almonds, free from hydrocyanic acid, and contains not less than one (1) per cent by volume of oil of bitter almonds.

2a. *Oil of bitter almonds,* commercial, is the volatile oil obtained from the seed of the bitter almond (*Amygdalus communis* L.), the apricot (*Prunus armeniaca* L.), or the peach (*Amygdalus persica* L.).

3. *Anise extract* is the flavoring extract prepared from oil of anise, and contains not less than three (3) per cent by volume of oil of anise.

3a. *Oil of anise* is the volatile oil obtained from the anise seed.

4. *Celery seed extract* is the flavoring extract prepared from celery seed or the oil of celery seed, or both, and contains not less than three-tenths (0.3) per cent by volume of oil of celery seed.

4a. *Oil of celery seed* is the volatile oil obtained from celery seed.

5. *Cassia extract* is the flavoring extract prepared from oil of cassia and contains not less than two (2) per cent by volume of oil of cassia.

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a The flavoring extracts described are intended solely for food purposes and are not to be confounded with similar preparations described in the Pharmacopœia for medicinal purposes.

5*a*. *Oil of cassia* is the lead-free volatile oil obtained from the leaves or bark of *Cinnamomum cassia* Bl., and contains not less than seventy-five (75) per cent by weight of cinnamic aldehyde.

6. *Cinnamon extract* is the flavoring extract prepared from oil of cinnamon, and contains not less than two (2) per cent by volume of oil of cinnamon.

6*a*. *Oil of cinnamon* is the lead-free volatile oil obtained from the bark of the Ceylon cinnamon (*Cinnamomum zeylanicum* Breyne), and contains not less than sixty-five (65) per cent by weight of cinnamic aldehyde and not more than ten (10) per cent by weight of eugenol.

7. *Clove extract* is the flavoring extract prepared from oil of cloves, and contains not less than two (2) per cent by volume of oil of cloves.

7*a*. *Oil of cloves* is the lead-free, volatile oil obtained from cloves.

8. *Ginger extract* is the flavoring extract prepared from ginger and contains in each one hundred (100) cubic centimeters, the alcohol-soluble matters from not less than twenty (20) grams of ginger.

9. *Lemon extract* is the flavoring extract prepared from oil of lemon, or from lemon peel, or both, and contains not less than five (5) per cent by volume of oil of lemon.

9*a*. *Oil of lemon* is the volatile oil obtained, by expression or alcoholic solution, from the fresh peel of the lemon (*Citrus limonum* L.), has an optical rotation (25° C.) of not less than +60° in a 100-millimeter tube, and contains not less than four (4) per cent by weight of citral.

10. *Terpeneless extract of lemon* is the flavoring extract prepared by shaking oil of lemon with dilute alcohol, or by dissolving terpeneless oil of lemon in dilute alcohol, and contains not less than two-tenths (0.2) per cent by weight of citral derived from oil of lemon.

10*a*. *Terpeneless oil of lemon* is oil of lemon from which all or nearly all of the terpenes have been removed.

11. *Nutmeg extract* is the flavoring extract prepared from oil of nutmeg, and contains not less than two (2) per cent by volume of oil of nutmeg.

11*a*. *Oil of nutmeg* is the volatile oil obtained from nutmegs.

12. *Orange extract* is the flavoring extract prepared from oil of orange, or from orange peel, or both, and contains not less than five (5) per cent by volume of oil of orange.

12*a*. *Oil of orange* is the volatile oil obtained, by expression or alcoholic solution, from the fresh peel of the orange (*Citrus aurantium* L.) and has an optical rotation (25° C.) of not less than +95° in a 100-millimeter tube.

13. *Terpeneless extract of orange* is the flavoring extract prepared by shaking oil of orange with dilute alcohol, or by dissolving terpeneless oil of orange in dilute alcohol, and corresponds in flavoring strength to orange extract.

13*a*. *Terpeneless oil of orange* is oil of orange from which all or nearly all of the terpenes have been removed.

14. *Peppermint extract* is the flavoring extract prepared from oil of peppermint, or from peppermint, or both, and contains not less than three (3) per cent by volume of oil of peppermint.

14*a*. *Peppermint* is the leaves and flowering tops of *Mentha piperita* L.

14*b*. *Oil of peppermint* is the volatile oil obtained from peppermint and contains not less than fifty (50) per cent by weight of menthol.

15. *Rose extract* is the flavoring extract prepared from otto of roses,

with or without red rose petals, and contains not less than four-tenths (0.4) per cent by volume of otto of roses.

15*a*. *Otto of roses* is the volatile oil obtained from the petals of *Rosa damascena* Mill., *R., centifolia,* L., or *R. moschata* Herrm.

16. *Savory extract* is the flavoring extract prepared from oil of savory, or from savory, or both, and contains not less than thirty-five hundredths (0.35) per cent by volume of oil of savory.

16*a*. *Oil of savory* is the volatile oil obtained from savory.

17. *Spearmint extract* is the flavoring extract prepared from oil of spearmint, or from spearmint, or both, and contains not less than three (3) per cent by volume of oil of spearmint.

17*a*. *Spearmint* is the leaves and flowering tops of *Mentha spicata* L.

17*b*. *Oil of spearmint* is the volatile oil obtained from spearmint.

18. *Star anise extract* is the flavoring extract prepared from oil of star anise, and contains not less than three (3) per cent by volume of oil of star anise.

18*a*. *Oil of star anise* is the volatile oil distilled from the fruit of the star anise (*Illicium verum* Hook).

19. *Sweet basil extract* is the flavoring extract prepared from oil of sweet basil, or from sweet basil, or both, and contains not less than one-tenth (0.1) per cent by volume of oil of sweet basil.

19*a*. *Sweet basil, basil,* is the leaves and tops of *Ocymum basilicum* L.

19*b*. *Oil of sweet basil* is the volatile oil obtained from basil.

20. *Sweet marjoram extract, marjoram extract,* is the flavoring extract prepared from the oil of marjoram, or from marjoram, or both, and contains not less than one (1) per cent by volume of oil of marjoram.

20*a*. *Oil of marjoram* is the volatile oil obtained from marjoram.

21. *Thyme extract* is the flavoring extract prepared from oil of thyme, or from thyme, or both, and contains not less than two-tenths (0.2) per cent by volume of oil of thyme.

21*a*. *Oil of thyme* is the volatile oil obtained from thyme.

22. *Tonka extract* is the flavoring extract prepared from tonka bean, with or without sugar or glycerin, and contains not less than one-tenth (0.1) per cent by weight of coumarin extracted from the tonka bean, together with a corresponding proportion of the other soluble matters thereof.

22*a*. *Tonka bean* is the seed of *Coumarouna odorata* Aublet (*Dipteryx odorata* (Aubl.) Willd.).

23. *Vanilla extract* is the flavoring extract prepared from vanilla bean, with or without sugar or glycerin, and contains in one hundred (100) cubic centimeters the soluble matters from not less than ten (10) grams of the vanilla bean.

23*a*. *Vanilla bean* is the dried, cured fruit of *Vanilla planifolia* Andrews.

24. *Wintergreen extract* is the flavoring extract prepared from oil of wintergreen, and contains not less than three (3) per cent by volume of oil of wintergreen.

24*a*. *Oil of wintergreen* is the volatile oil distilled from the leaves of the *Gaultheria procumbens* L.

C. EDIBLE VEGETABLE OILS AND FATS.

1. *Olive oil* is the oil obtained from the sound, mature fruit of the cultivated olive tree (*Olea europoea* L.) and subjected to the usual refining processes; is free from rancidity; has a refractive index (25° C.) not less than one and forty-six hundred and sixty ten-thousandths (1.4660) and not exceeding one and forty-six hundred and

eighty ten-thousandths (1.4680); and an iodin number not less than seventy-nine (79) and not exceeding ninety (90).

2. *Virgin olive oil* is olive oil obtained from the first pressing of carefully selected, hand-picked olives.

3. *Cotton-seed oil* is the oil obtained from the seeds of cotton plants (*Gossypium hirsutum* L., *G. barbadense* L., or *G. herbaceum* L.) and subjected to the usual refining processes; is free from rancidity; has a refractive index (25° C.) not less than one and forty-seven hundred ten-thousandths (1.4700) and not exceeding one and forty-seven hundred and twenty-five ten-thousandths (1.4725); and an iodin number not less than one hundred and four (104) and not exceeding one hundred and ten (110).

4. *"Winter-yellow" cotton-seed oil* is expressed cotton-seed oil from which a portion of the stearin has been separated by chilling and pressure, and has an iodin number not less than one hundred and ten (110) and not exceeding one hundred and sixteen (116).

5. *Peanut oil, arachis oil, earthnut oil,* is the oil obtained from the peanut (*Arachis hypogæa* L.) and subjected to the usual refining processes; is free from rancidity; has a refractive index (25° C.) not less than one and forty-six hundred and ninety ten-thousandths (1.4690) and not exceeding one and forty-seven hundred and seven ten-thousandths (1.4707); and an iodin number not less than eighty-seven (87) and not exceeding one hundred (100).

6. *"Cold-drawn" peanut oil* is peanut oil obtained by pressure without heating.

7. *Sesame oil, gingili oil, teel oil,* is the oil obtained from the seeds of the sesame plants (*Sesamum orientale* L. and *S. radiatum* Schum. and Thonn.) and subjected to the usual refining processes; is free from rancidity; has a refractive index (25° C.) not less than one and forty-seven hundred and four ten-thousandths (1.4704) and not exceeding one and forty-seven hundred and seventeen ten-thousandths (1.4717), and an iodin number not less than one hundred and three (103) and not exceeding one hundred and twelve (112).

8. *"Cold-drawn" sesame oil* is sesame oil obtained by pressure without heating.

9. *Poppy-seed oil* is the oil obtained from the seed of the poppy (*Papaver somniferum* L.) subjected to the usual refining processes and free from rancidity.

10. *White poppy-seed oil, or "cold-drawn" poppy-seed oil* is poppy-seed oil of the first pressing without heating.

11. *Coconut oil* is the oil obtained from the kernels of the coconut (*Cocos nucifera* L.) and subjected to the usual refining processes and free from rancidity.

12. *Cochin oil* is coconut oil prepared in Cochin (Malabar).

13. *Ceylon oil* is coconut oil prepared in Ceylon.

14. *Copra oil* is coconut oil prepared from copra, the dried kernels of the coconut.

15. *Rape-seed oil, colza oil,* is the oil obtained from the seeds of the rape plant (*Brassica napus* L.) and subjected to the usual refining processes and free from rancidity.

16. *"Cold-drawn" rape-seed oil* is rape-seed oil obtained by the first pressing without heating.

17. *Sunflower oil* is the oil obtained from the seeds of the sunflower (*Helianthus annuus* L.) and subjected to the usual refining processes and free from rancidity.

18. *'Cold-drawn" sunflower oil* is sunflower oil obtained by the first pressing without heating.

19. *Maize oil, corn oil,* is the oil obtained from the germ of the

maize (*Zea mays* L.) and subjected to the usual refining processes and free from rancidity.

20. *Cocoa butter, cacao butter*, is the fat obtained from roasted, sound cocoa beans, and subjected to the usual refining processes; is free from rancidity; has a refractive index (40° C.) not less than one and forty-five hundred and sixty-six ten-thousandths (1.4566) and not exceeding one and forty-five hundred and ninety-eight ten-thousandths (1.4598), an iodin number not less than thirty-three (33) and not exceeding thirty-eight (38); and a melting point not lower than 30° C. nor higher than 35° C.

21. *Cotton-seed oil stearin* is the solid product made by chilling cotton-seed oil and separating the solid portion by filtration, with or without pressure, and having an iodin number not less than eighty-five (85) and not more than one hundred (100).

E. Tea, Coffee, and Cocoa Products.

a. TEA.

1. *Tea* is the leaves and leaf buds of different species of *Thea*, prepared by the usual trade processes of fermenting, drying, and firing; meets the provisions of the act of Congress approved March 2, 1897, and the regulations made in conformity therewith (Treasury Department Circular 16, February 6, 1905); conforms in variety and place of production to the name it bears; and contains not less than four (4) nor more than seven (7) per cent of ash.

b. COFFEE.

1. *Coffee* is the seed of *Coffea arabica* L. or *Coffea liberica* Bull., freed from all but a small portion of its spermoderm, and conforms in variety and place of production to the name it bears.

2. *Roasted coffee* is coffee which by the action of heat has become brown and developed its characteristic aroma, and contains not less than ten (10) per cent of fat and not less than three (3) per cent of ash.

c. COCOA AND COCOA PRODUCTS.

1. *Cocoa beans* are the seeds of the cacao tree, *Theobroma cacao* L.

2. *Cocoa nibs, cracked cocoa,* is the roasted, broken cocoa bean freed from its shell or husk.

3. *Chocolate, plain chocolate, bitter chocolate, chocolate liquor, bitter chocolate coatings,* is the solid or plastic mass obtained by grinding cocoa nibs without the removal of fat or other constituents except the germ, and contains not more than three (3) per cent of ash insoluble in water, three and fifty-hundredths (3.50) per cent of crude fiber, and nine (9) per cent of starch, and not less than forty-five (45) per cent of cocoa fat.

4. *Sweet chocolate, sweet chocolate coatings,* is chocolate mixed with sugar (sucrose), with or without the addition of cocoa butter, spices, or other flavoring materials, and contains in the sugar-and fat-free residue no higher percentage of either ash, fiber, or starch than is found in the sugar- and fat-free residue of chocolate.

5. *Cocoa, powdered cocoa,* is cocoa nibs, with or without the germ, deprived of a portion of its fat and finely pulverized, and contains percentages of ash, crude fiber, and starch corresponding to those in chocolate after correction for fat removed.

6. *Sweet cocoa, sweetened cocoa,* is cocoa mixed with sugar (sucrose), and contains not more than sixty (60) per cent of sugar (sucrose), and in the sugar- and fat-free residue no higher percentage of either ash, crude fiber, or starch than is found in the sugar- and fat-free residue of chocolate.

F. Beverages.

a. Fruit juices—fresh, sweet, and fermented.

1. Fresh and 2. Sweet.

(Schedules in preparation.)

3. Fermented fruit juices.

1. *Wine* is the product made by the normal alcoholic fermentation of the juice of sound, ripe grapes, and the usual cellar treatment, and contains not less than seven (7) nor more than sixteen (16) per cent of alcohol, by volume, and, in one hundred (100) cubic centimeters (20° C.), not more than one-tenth (0.1) gram of sodium chlorid nor more than two-tenths (0.2) gram of potassium sulphate; and for red wine not more than fourteen hundredths (0.14) gram, and for white wine not more than twelve hundredths (0.12) gram of volatile acids produced by fermentation and calculated as acetic acid. *Red wine* is wine containing the red coloring matter of the skins of grapes. *White wine* is wine made from white grapes or the expressed fresh juice of other grapes.

2. *Dry wine* is wine in which the fermentation of the sugars is practically complete and which contains, in one hundred (100) cubic centimeters (20° C.), less than one (1) gram of sugars and for dry red wine not less than sixteen hundredths (0.16) gram of grape ash and not less than one and six-tenths (1.6) grams of sugar-free grape solids, and for dry white wine not less than thirteen hundredths (0.13) gram of grape ash and not less than one and four-tenths (1.4) grams of sugar-free grape solids.

3. *Fortified dry wine* is dry wine to which brandy has been added but which conforms in all other particulars to the standard of dry wine.

4. *Sweet wine* is wine in which the alcoholic fermentation has been arrested, and which contains, in one hundred (100) cubic centimeters (20° C.), not less than one (1) gram of sugars, and for sweet red wine not less than sixteen hundredths (0.16) gram of grape ash, and for sweet white wine not less than thirteen hundredths (0.13) gram of grape ash.

5. *Fortified sweet wine* is sweet wine to which wine spirits have been added. By act of Congress, "sweet wine" used for making fortified sweet wine and "wine spirits" used for such fortification are defined as follows (sec. 43, Act of October 1, 1890, 26 Stat., 567, as amended by section 68, Act of August 27, 1894, 28 Stat., 509, and further amended by Act of Congress approved June 7, 1906): "That the wine spirits mentioned in section 42 of this act is the product resulting from the distillation of fermented grape juice to which water may have been added prior to, during, or after fermentation, for the sole purpose of facilitating the fermentation and economical distillation thereof, and shall be held to include the products from grapes or their residues, commonly known as grape brandy; and the pure sweet wine, which may be fortified free of tax, as provided in said section, is fermented grape juice only, and shall contain no other substance whatever introduced before, at the time of, or after fermentation, except as herein expressly

provided; and such sweet wine shall contain not less than four per centum of saccharine matter, which saccharine strength may be determined by testing with Balling's saccharometer or must scale, such sweet wine, after the evaporation of the spirits contained therein, and restoring the sample tested to original volume by addition of water: *Provided,* That the addition of pure boiled or condensed grape must or pure crystallized cane or beet sugar or pure anhydrous sugar to the pure grape juice aforesaid, or the fermented product of such grape juice prior to the fortification provided by this Act for the sole purpose of perfecting sweet wine according to commercial standard, or the addition of water in such quantities only as may be necessary in the mechanical operation of grape conveyers, crushers, and pipes leading to fermenting tanks, shall not be excluded by the definition of pure sweet wine aforesaid: *Provided, however,* That the cane or beet sugar, or pure anhydrous sugar, or water, so used shall not in either case be in excess of ten (10) per centum of the weight of the wine to be fortified under this Act: *And provided further,* That the addition of water herein authorized shall be under such regulations and limitations as the Commissioner of Internal Revenue, with the approval of the Secretary of the Treasury, may from time to time prescribe; but in no case shall such wines to which water has been added be eligible for fortification under the provisions of this Act where the same, after fermentation and before fortification, have an alcoholic strength of less than five per centum of their volume."

6. *Sparkling wine* is wine in which the after part of the fermentation is completed in the bottle, the sediment being disgorged and its place supplied by wine or sugar liquor, and which contains, in one hundred (100) cubic centimeters (20° C.), not less than twelve hundredths (0.12) gram of grape ash.

7. *Modified wine, ameliorated wine, corrected wine,* is the product made by the alcoholic fermentation, with the usual cellar treatment, of a mixture of the juice of sound, ripe grapes with sugar (sucrose), or a sirup containing not less than sixty-five (65) per cent of sugar (sucrose), and in quantity not more than enough to raise the alcoholic strength after fermentation, to eleven (11) per cent by volume.

8. *Raisin wine* is the product made by the alcoholic fermentation of an infusion of dried or evaporated grapes, or of a mixture of such infusion or of raisins with grape juice.

b. MEAD, ROOT BEER, ETC.

(Schedule in preparation.)

c. MALT LIQUORS.

(Schedule in preparation.)

d. SPIRITUOUS LIQUORS.

(Schedule in preparation.)

e. CARBONATED WATERS, ETC.

(Schedule in preparation.)

G. VINEGAR.

1. *Vinegar, cider vinegar, apple vinegar,* is the product made by the alcoholic and subsequent acetous fermentations of the juice of apples, is lævo-rotatory, and contains not less than four (4) grams of acetic acid, not less than one and six-tenths (1.6) grams of apple solids, of

which not more than fifty (50) per cent are reducing sugars, and not less than twenty-five hundredths (0.25) gram of apple ash in one hundred (100) cubic centimeters (20° C.); and the water-soluble ash from one hundred (100) cubic centimeters (20° C.) of the vinegar contains not less than ten (10) milligrams of phosphoric acid (P_2O_5), and requires not less than thirty (30) cubic centimeters of decinormal acid to neutralize its alkalinity.

2. *Wine vinegar, grape vinegar,* is the product made by the alcoholic and subsequent acetous fermentations of the juice of grapes and contains, in one hundred (100) cubic centimeters (20° C.), not less than four (4) grams of acetic acid, not less than one (1.0) gram of grape solids, and not less than thirteen hundredths (0.13) gram of grape ash.

3. *Malt vinegar* is the product made by the alcoholic and subsequent acetous fermentations, without distillation, of an infusion of barley malt or cereals whose starch has been converted by malt, is dextro-rotatory, and contains, in one hundred (100) cubic centimeters (20° C.), not less than four (4) grams of acetic acid, not less than two (2) grams of solids, and not less than two-tenths (0.2) gram of ash; and the water-soluble ash from one hundred (100) cubic centimeters (20° C.) of the vinegar contains not less than nine (9) milligrams of phosphoric acid (P_2O_5), and requires not less than four (4) cubic centimeters of decinormal acid to neutralize its alkalinity.

4. *Sugar vinegar* is the product made by the alcoholic and subsequent acetous fermentations of solutions of sugar, sirup, molasses, or refiners' sirup, and contains, in one hundred (100) cubic centimeters (20° C.), not less than four (4) grams of acetic acid.

5. *Glucose vinegar* is the product made by the alcoholic and subsequent acetous fermentations of solutions of starch sugar or glucose, is dextro-rotatory, and contains, in one hundred (100) cubic centimeters (20° C.), not less than four (4) grams of acetic acid.

6. *Spirit vinegar, distilled vinegar, grain vinegar,* is the product made by the acetous fermentation of dilute distilled alcohol, and contains, in one hundred (100) cubic centimeters (20° C.), not less than four (4) grams of acetic acid.

III. SALT.

1. *Table salt, dairy salt,* is fine-grained crystalline salt containing on a water-free basis, not more than one and four-tenths (1.4) per cent of calcium sulphate ($CaSO_4$), nor more than five-tenths (0.5) per cent of calcium and magnesium chlorids ($CaCl_2$ and $MgCl_2$), nor more than one-tenth (0.1) per cent of matters insoluble in water.

IV. PRESERVATIVES AND COLORING MATTERS.

(Schedules in preparation.)

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